Supreme Court, U.S.
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No. _____

OFFICE

In The

Supreme Court of the United States

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Presentment Clause of the United States Constitution is violated by the National Vaccine Injury Compensation Program, which

A) allows a child injured by the administration of a vaccine to receive compensation for those injuries, without full proof of causation or negligence, if that vaccine and those injuries are included in a statutory Table listing vaccines, related injuries and conditions, and other definitional provisions; and

B) gives unlimited authority to the Secretary of Health and Human Services to change through rulemaking the injuries and conditions included in the statutory Table, and so change fundamentally the scope and operation of the Program as originally enacted by Congress.

2. Whether the National Vaccine Injury Compensation Program unconstitutionally delegates legislative power to the Secretary of Health and Human Services by giving her complete authority to replace the statutory Table that defines central mechanism of Program's compensation scheme, unrestrained by any substantive conditions established by Congress.

3. Whether a trial judge's general "gatekeeping" function concerning the admissibility of expert testimony, as described by this Court in *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), gives that judge, in the context of proceedings under a special compensation scheme created by Congress, the discretion to impose a

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higher standard of proof than that provided by Congress for such compensation.

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PETITION FOR WRIT OF CERTIORARI

Petitioner Michele Terran, on behalf of her minor daughter, Julie Terran, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The decision of a Special Master of the Court of Federal Claims (App. 59a) denying petitioner's claim for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 – 34, was entered January 23, 1998 and is unreported. The judgment of the Court of Federal Claims (App. 41a) affirming the decision of the Special Master was entered July 10, 1998 and is reported at 41 Fed. Cl. 330 (1998). The opinion of the United States Court of Appeals for the Federal Circuit (App. 1a) affirming the judgment of the Court of Federal Claims was entered on October 27, 1999, and is reported at 195 F.3d 1302. The court of appeals denied petitions for rehearing and for rehearing *en banc* on February 2, 2000 (App. 93a). On March 6, 2000, the court of appeals granted petitioner's motion to recall and stay the mandate (App. 95a).

JURISDICTION

The court of appeals entered its decision on October 27, 1999. On December 13, 1999, petitioner timely filed a petition for rehearing and a petition for rehearing *en banc*, which was denied by the court of appeals on February 2, 2000. This Court has jurisdiction under 28 U.S.C. § 1257.

CONSTITUTIONAL PROVISION INVOLVED

This case involves the Presentment and Bicameralism provisions of Article I of the United States Constitution, which provide: "Every Bill which shall have passed the House of Representatives and the Senate, shall, before it become a Law, be presented to the President of the

United States; if he approve he shall sign it, but if not he shall return it . . . . " U.S. CONST. art. I, § 7, cl. 2.

STATUTE AND REGULATION INVOLVED

The statute involved in this case is the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 – 34 ("the Compensation Program"), which is reproduced in pertinent part at App. 119a. The regulation involved in this case is codified at 42 C.F.R. pt. 100 (1995), which is reproduced in pertinent part at App. 176a.

STATEMENT OF THE CASE

This case merits review by this Court because the questions it presents arise from a legislative scheme that, in a surprisingly stark fashion, crosses fundamental boundaries of governmental power drawn by the Constitution and well-recognized by this Court, most recently in *Clinton v. City of New York*, 524 U.S. 417 (1998). The need for this Court's attention to this case is particularly acute because the legislation at issue, the National Vaccine Injury Compensation Program, provides for a judicial process essentially only through the Court of Appeals for the Federal Circuit, foreclosing diverse appellate consideration and a possible circuit split. Thus, the precedent to be set by this case is critically important not only to the body of constitutional principles at issue, but to the operation of that Program and to the rules that govern a sizeable and technical body of law.

Judge Plager, dissenting from the panel opinion below, captured the essence of the constitutional issue at stake here:

> In this case, Congress purported to provide for the amendment of existing legislation, which was otherwise valid and enforceable by the courts of the United States, in a manner different from that provided in the Constitution, namely by authorizing an Executive Branch official to do it. That effort must necessarily fail . . . .

. . . .

> Given the clarity with which the Constitution speaks to this question, and the Supreme Court's unequivocal honoring of the Presentment Clause in *Chadha* and *Clinton*, one might suppose that this would be a not-difficult case to decide.

195 F.3d 1317-18 (Plager, J., dissenting) (App. 30a, 32a).

1. The National Vaccine Injury Compensation Program Devised by Congress

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 *et seq.* ("the Vaccine Act"), is not unfamiliar to the Court, which considered it in the context of other, unrelated issues in *Shalala v. Whitecotton*, 514 U.S. 268 (1995). This case arises from the second of the two parts of the Vaccine Act, the Compensation Program.[1]

Under Part 2 of the Vaccine Act, 42 U.S.C. §§ 300aa-10-34 (App. 119a-175a), the Compensation Program, victims of vaccine-related injuries may receive compensation from a federal fund financed by a tax on vaccines through adjudication of the claim before a special master of the United States Court of Federal Claims. Claimants are not barred from pursuing compensation in a traditional tort proceeding if dissatisfied with the result reached by the special master, but petition and review under the Act are prerequisite to such a suit. *See* 42 U.S.C. §§ 300aa-11(a) (App. 119a-122a), 300aa-21 (App. 162a-164a). The procedure before the special master affords two distinct avenues of compensation: the "Table

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[1] The first part, the National Vaccine Program, established a new program within the Department of Health and Human Services to improve vaccine research and development while enhancing efforts to prevent adverse reactions to vaccines. *See* 42 U.S.C. §§ 300aa-1 – 6 (App. 107a-118a).

injury," or the off-the-Table injury, also called "causation in fact." 145 F.3d at 1307 (App. 6a).

The Compensation Program arose from two congressional concerns: that tort liability resulting from injuries caused by the administration of childhood vaccines "might drive up the prices of vaccines and discourage vaccine manufacturers from staying in this market; and that normal tort litigation might leave many sufferers of vaccine-caused injuries uncompensated." 195 F.3d at 1307 (App. 5a). *See also Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994). This dilemma was compounded by "State immunization laws [which] require that virtually all children be vaccinated against each of the seven common childhood diseases before they enter school." NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986, H.R. REP. NO. 99-908, at 5 (1986) ("House Report").[2]

Essentially, the Compensation Program is "a scheme of recovery [for vaccine-related injuries] designed to work faster and with greater ease than the civil tort system." *Whitecotton*, 514 U.S. at 269. Most importantly for our purposes here, Congress devised the Compensation Program understanding that children may have severely disabling, or even fatal, reactions to common vaccines such as DPT (diphtheria, pertussis, tetanus), but that "it is not always possible to predict who they will be or what reactions they will have." House Report at 6. *See also* Lisa J. Steel, Note, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?* 63 GEO. WASH. L. REV. 144, 145 (1994) ("Before a child is given her first vaccine, it is almost impossible to predict what reaction the child will have to the vaccine.").

A key policy issue that shapes both the Table and off-the-Table compensation methods concerns how to treat scientific uncertainty regarding the incidence and type of vaccine reactions. Thus, Congress's judgments about the

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[2] Those diseases are polio, measles, mumps, rubella, diphtheria, pertussis, and tetanus. House Report at 5.

capacity of vaccines to cause certain injuries, judgments about the kinds of injuries that should be compensated under the Program, and judgments about how to handle cases when science provides no clear guidance on the capacity of vaccines to cause the injuries suffered by a particular child are evident in both the Table and off-the-Table compensation schemes.

A. The "Table Injury"

Perhaps the most distinctive feature of the Compensation Program is the Vaccine Injury Table ("the Table"), which lists medical conditions that may result from the administration of a particular vaccine along with a time period in which the symptoms of that condition must become manifest. 42 U.S.C. § 300aa-14(a) (App. 139a-142a). The statute also provides "Qualifications and Aids to Interpretation" ("QAIs"), which define the terms used in the Table. 42 U.S.C. § 300aa-14(b) (App. 142a-144a). If a preponderance of the evidence shows that a claimant's injuries following administration of a vaccine are of the type listed in the Table and were manifested within the specified period, 42 U.S.C. §§ 300aa-13(a)(1)(A) (App. 136a), 300aa-11(c)(1)(C)(i) (App. 124a-125a), and if "there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine," 42 U.S.C. § 300aa-13(a)(1)(B) (App. 136a), then she is entitled to compensation under the Act without submitting further proof of causation. 42 U.S.C. § 300aa-14(a) (App. 139a-142a). *See* 195 F.3d at 1307-09 (App. 5a-9a).

Although a presumption of causation under the Table requires that there be no preponderance of the evidence showing some non-vaccine cause for the injury, Congress ensured that the claimant does not have to overcome scientific uncertainty concerning such other causes by excluding "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" from consideration as a cause of the injury

unrelated to a vaccine. 42 U.S.C. § 300aa-13(a)(2)(A) (App. 137a). As the House Energy and Commerce Committee emphasized:

> In its determination that the injury was not caused by factors unrelated to the vaccine, the court may rely on evidence of other infections, traumas, or conditions but is not to include speculative or hypothetical matters or explanations. If the injury is not demonstrated to have been caused by other, defined illnesses or factors and the injury is demonstrated to have met the other requirements of Section 2111 and the Table, the injury is to be deemed to be vaccine-related.

House Report at 18.

Similar congressional judgments as to how to treat scientific uncertainty about which injuries are caused by vaccines can also be seen clearly in the Table itself and the related QAIs. A helpful illustration is the provision relating to encephalopathy, a condition from which Julie Terran suffers, and which is central to her right to recover in this case.

Encephalopathy is a condition listed on the Table in relation to several vaccines, including DPT. 42 U.S.C. § 300aa-14(a) (App. 139a-142a). It is undisputed that encephalopathy, as a medical term, simply means "[a]ny dysfunction of the brain." TABER'S CYCLOPEDIC MEDICAL DICTIONARY 586 (16th ed. 1989). *See also O'Connell v. Shalala*, 79 F.3d 170, 174 n.3 (1st Cir. 1996) (quoting STEDMAN'S MEDICAL DICTIONARY 508 (25th ed. 1990)). Congress adopted this understanding of the term for use in the Compensation Program. 42 U.S.C. § 300aa-14(b)(3)(A) (App. 143a-144a) ("The term 'encephalopathy' means any significant acquired abnormality of, or injury to, or impairment of function of the brain.").

Adopting encephalopathy as a covered condition obviously gave a broad scope to the Compensation Program, yet Congress went even further in the QAIs, where it made clear that *all* forms of encephalopathy were to be

covered, even those that "may be temporary with complete recovery, or may result in various degrees of permanent impairment." 42 U.S.C. § 300aa-14(b)(3)(A) (App. 143a-144a). And though Congress intended that injuries shown by a preponderance of the evidence not to be caused by a vaccine were not to be covered by the Program, 42 U.S.C. § 300aa-14(b)(3)(B) (App. 144a), it also made the judgment that when "it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table." 42 U.S.C. § 300aa-14(b)(3)(B) (App. 144a). As written by Congress, then, the Compensation Program did not permit scientific uncertainty concerning the causation of encephalopathy to deprive a claimant of compensation for that condition.

B. Compensation "Off-the-Table"

The Compensation Program provides a second avenue for compensation, "off-the-Table," when a vaccine listed on the Table has caused a condition not listed on the Table or when the first symptom of a condition listed on the Table did not occur within the timeframes set by the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) & (II) (App. 125a). Though compensation "off-the-Table" is often called "causation in fact," that appellation is not used in the statute and does not fully describe the more nuanced standard for compensation that Congress actually established. Under that standard, which follows the same two-part structure as a Table injury, a claimant is entitled to compensation when a vaccine is shown to have caused the condition suffered by "a preponderance of the evidence," 42 U.S.C. § 300aa-13(a) (App. 136a-137a) *and* "there is not a preponderance of the evidence that the . . . condition . . . is due to factors unrelated to the administration of the vaccine." 42 U.S.C. § 300aa-13(a)(1) (App. 136a). *See also Bunting v. Secretary of HHS*, 931 F.2d 867, 872 (Fed. Cir. 1991). Again, scientific uncertainty concerning causation cannot defeat the claim. 42 U.S.C.

§ 300aa-13(a)(2)(A) (App. 136a-138a). *See also* House Report at 18; *Bunting*, 931 F.2d at 873.

2. The Compensation Program as Revised by the Secretary

The other distinctive feature of the Compensation Program is its provision giving the Secretary of Health and Human Services (the "Secretary") the power, by rulemaking, to revise the Table by adding to or deleting from the list of compensable injuries or conditions or by changing the time periods in which those injuries or conditions must become manifest. 42 U.S.C. § 300aa-14(c) (App. 144a-145a).[3] In delegating this unique power to the Secretary,[4] Congress was clearly motivated by its expectation that the limits of scientific understanding of how vaccines cause various adverse conditions in children would recede in the face of future research. *See* House Report at 18 ("The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary . . . may propose to revise the Table.").

To generally assist in the effort to develop safer childhood vaccines and to advise the Secretary regarding changes to the Table, the Vaccine Act also establishes the Advisory Commission on Childhood Vaccines (the "Advisory Commission"), comprised of health professionals,

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[3] This power to revise the Table includes the power to revise the related QAIs. *O'Connell*, 79 F.3d at 177. *See* 42 U.S.C. § 300aa-14(c)(4) (App. 145a) (providing that, if the Table is revised, the corresponding QAIs become invalid unless the Secretary specifically allows them to remain valid).

[4] The First Circuit called it "a rather odd approach because it authorizes the Secretary, in effect, to amend the statutorily enacted Table by way of administrative rulemaking." *O'Connell*, 79 F.3d at 173.

lawyers, and representatives of children injured by vaccines. 42 U.S.C. § 300aa-19 (App. 158a-161a). The Vaccine Act prohibits the Secretary from promulgating regulations modifying the Table without first allowing the Advisory Commission to review the proposed changes and make recommendations. 42 U.S.C. § 300aa-14(d) (App. 146a-147a). The Vaccine Act sets out no guidance for or limits on the discretion of the Advisory Commission in making its recommendations.

Finally, Congress included in an uncodified section of the Vaccine Act a mandate to the Secretary to review existing medical literature in consultation with the Advisory Commission and to commission studies by the Institute of Medicine of the National Academy of Sciences (the "IOM") concerning the relationship between vaccines and various illnesses or conditions. Pub. Law No. 99-660 § 312, 101 stat. 1330-221 (1987) (App. 110a-115a). Not later than three years after enactment of the Vaccine Act, the Secretary was to publish her findings concerning whether those illnesses or conditions "can reasonably be determined in some circumstances to be caused" by vaccines and the circumstances in which such injuries or conditions can be caused. Pub. Law No. 99-660 § 312(b), (d) (App. 111a-112a). At the same time as those findings are published, the Secretary is to propose regulations to amend the Table "as a result of such findings." Pub. Law No. 99-660 § 312(c) (App. 112a).

The IOM published its report, Adverse Effects of Pertussis and Rubella Vaccines, based on its review of the scientific literature on August 27, 1991 (the "IOM Report"),[5] which included no original research conducted by the IOM. *See* 57 Fed. Reg. 36,878 (1992). Indeed, "[t]he IOM cited many gaps and limitations of knowledge." 60

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[5] The IOM undertook this review through a committee of 11 experts. 57 Fed. Reg. 36,878. "The Report is an inventory and review of *existing* information about adverse reactions following immunization." 57 Fed. Reg. 36,878 (emphasis added).

Fed. Reg. 7678, 7683 (1995). Slightly less than a year later, the Secretary published a Notice of Proposed Rulemaking to amend the Table based on the IOM Report and the recommendations of the Advisory Commission and other bodies.[6] *See also* 57 Fed. Reg. 36,878.

The Final Rule was published nearly three years later. 60 Fed. Reg. 7678. That three-year span is significant because it illuminates the extent of the "gaps and limitations of knowledge" on which the IOM Report, and the Secretary's rulemaking, was based. Specifically, "the only systematic study of chronic nervous system dysfunctions after DPT" available was the British National Childhood Encephalopathy Study ("NCES"), published in 1983. 60 Fed. Reg. 7685. After the Secretary had received comments on the proposed rule, she became aware of the imminent release of a 10-year follow-up study to the NCES. Given the central role of the NCES, further action was delayed in the rulemaking until that follow-up report could be analyzed and incorporated into the revision of the Table. 60 Fed. Reg. 7678.

The changes made by the Secretary to the statutory Table were significant, essentially amounting to a full-scale revision. In Julie Terran's case in particular, they were outcome-determinative, totally removing her injuries from the Table. Two specific amendments to the Table altered her rights to recovery. First, the Secretary deleted residual seizure disorder from the injuries associated with DPT vaccines. *Compare* 42 U.S.C. § 300aa-14(a) (App. 139a-142a) (the statutory Table) *with* 42 C.F.R. § 100.3(a) (1995) (the Secretary's Table) (App. 177a-179a). Second, for purposes of her revision of the Table, the Secretary severely cut from the classic medical definition of encephalopathy to include only "acute" encephalopathy, which the Secretary defined to require "a significantly decreased level of consciousness lasting for at least 24

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[6] *See O'Connell*, 79 F.3d at 174 (describing this process).

hours." *Compare* 42 U.S.C. § 300aa-14(b)(3) (App. 143a-144a) *with* 42 C.F.R. § 100.3(b)(2) (App. 180a-183a).

The Secretary's rationale for these changes was succinctly stated:

> The IOM concluded that "the evidence is insufficient to indicate a causal relation between vaccines containing pertussis" and certain adverse events. Because the evidence was determined "insufficient," the Department concluded that it could not "reasonably determine" that a causal connection exists, and the Table is being revised accordingly.

60 Fed. Reg. 7681.

Consistent with her focus on acute encephalopathy alone, the Secretary also reversed Congress's inclusion of temporary encephalopathy as a covered condition. *Compare* 42 U.S.C. § 300aa-14(b)(3)(A) (App. 143a-44a) *with* 42 C.F.R. § 100.3(b)(2)(ii) (App. 183a). Curiously, in light of the Secretary's reliance on the state of scientific uncertainty as the justification to limit the injuries and conditions covered by the Table, she left untouched the provision that presumes an encephalopathy *is* a Table condition if "it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy." 42 C.F.R. § 100.3(b)(2)(iii) (App. 183a).

3. The Proceedings Below

A. The Decision of the Special Master

On July 12, 1995, after the Secretary's Table had replaced the original Table enacted by Congress, Julie Terran's mother filed a claim for compensation on Julie's behalf, based on Julie's residual seizure disorder ("RSD") and encephalopathy. App. 184a-194a. Most of the essential facts were not in dispute.

The record shows that Julie was born a normal, healthy child, a fact established in part as a result of various tests involving her brain, including an MRI, that

Julie underwent due to an unrelated medical problem before she received the vaccination at issue. These tests established that "she had no brain abnormalities," and had "normal brain structure" before the vaccine was administered. App. 62a. The manifestation of Julie's injuries began the day after her third DPT vaccination, on August 11, 1992, when she suffered her first seizure. App. 61a. She was rushed to the hospital the next day after suffering four more seizures. App. 61a. Her seizures, of varying duration and intensity,[7] have continued to the present. App. 61a.

As she grew older, Julie's broader neurological problems became evident. In November 1993, she had a "borderline passing score" on a standard developmental screening test, and she is currently mentally retarded. App. 62a, 81a.

MRIs after the administration of the vaccine continued to confirm that Julie had "no structural pathology in her brain." App. 62a. And in the proceedings before the special master, the Secretary, as the Respondent, requested that Julie have two separate "genetic workups," the results of which "were entirely normal." App. 62a.

The decision of the special master was based on Julie's medical records, plus the testimony of one fact witness (her pediatrician) and two expert witnesses (one for each party). App. 63a-72a. The special master's analysis began with the conclusions that neither Julie's RSD nor her type of encephalopathy were on the Table after the Secretary's revision of the Table. App. 72a-73a. Moving on to evaluate Julie's case as an "off-the-Table" or "causation-in-fact" claim, the special master concluded that "Julie suffers from a seizure disorder" and from "a

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[7] For example, Julie's first seizure lasted about seven seconds, while on September 12, 1992, she suffered from a seizure that lasted approximately 50 minutes, even while she was on an anti-convulsant medication. App. 61a.

chronic encephalopathy," and that she is "mentally retarded and developmentally delayed." App. 81a. He further concluded that the DPT vaccine can cause these conditions. App. 88a. The special master noted that the vaccine Julie had received had come from a " 'hot lot' that had a history of causing injuries in children," a fact he found "to weigh heavily in favor of [her] claim." App. 87a. Finally, the special master rejected *in toto* the position of the Secretary's expert that Julie's injuries were caused by some unnamed disorder, a "disorder," in the words of the special master, that "cannot be observed chemically, radiographically, electrically, genetically, or even visually upon death." App. 89a. As a result, the special master concluded that Julie's injuries were not caused by "any factor unrelated to the administration of the vaccine." App. 89a.

At the same time, the special master rejected the testimony of Julie's expert that DPT caused Julie's injuries and his explanation of how that injury was caused because he concluded, applying *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), that the expert's opinion concerning the mechanism by which such injuries are caused was not generally accepted in the scientific community and had not been subjected to peer review, and so was unreliable. App. 85a-87a. Ultimately, the special master denied Julie's claim because she suffered from afebrile, as opposed to febrile, seizures, App. 87a, relying on a conclusion in the IOM Report that there was "a causal relation between DPT and *febrile* seizures," but that "*the evidence remains insufficient to indicate* the presence or absence of a causal relation between DPT and chronic nervous system dysfunction under any other circumstances." App. 83a (emphases in original) (citation omitted).

B. The Decision of the Court of Federal Claims

Petitioner sought review of the special master's decision in the Court of Federal Claims, raising both legal and

factual challenges. The court held that it lacked jurisdiction to consider Petitioner's constitutional argument that the Vaccine Act's scheme for amending the Table violated the Presentment Clause. 41 Fed. Cl. at 334 (App. 47a-48a). The court also rejected other non-constitutional challenges to the Secretary's Table that are no longer at issue. *Id.* at 335 (App. 48a-49a). Finally, the court upheld the special master's rejection of Petitioner's off-the-Table claim, essentially echoing the reasoning of the special master. *Id.* (App. 49a-50a).

C. The Decision of the Court of Appeals

On October 27, 1999, a divided panel of the Federal Circuit affirmed the Court of Federal Claims' ruling over a dissent by Judge Plager. At the outset, the court of appeals unanimously disagreed with the Court of Federal Claims' conclusion that it lacked jurisdiction to hear a constitutional challenge to the Secretary's Table. 195 F.3d at 1309-10 (App. 12a-13a).

Addressing the constitutional issue for the first time, the majority held that the Presentment Clause is not violated by the Compensation Program because the Program "does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations." *Id.* at 1312 (App. 18a-19a). The majority reasoned that the original Table remains on the books and is applicable to all claims made before the Secretary's Table was promulgated. The Secretary's Table, according to the majority, thus promulgated "an entirely new vaccine injury table" that did not really "amend" the statutory Table. *Id.* Rather, the majority concluded, Congress had designed the Compensation Program's scheme to change the Table like a "sunset" provision in which the original Table "would cease to apply to newly filed petitions when the Secretary promulgated a revised injury table." *Id.* at 1313 (App. 19a). This analogy to sunset provisions, in the mind of the majority, made this case closer to *Field v. Clark*, 143 U.S. 649 (1892),

than to this Court's recent decision in *Clinton v. City of New York*, 524 U.S. 417 (1998).

The court went on to reject the related argument that the Secretary's power to revise the Table violated the non-delegation doctrine, holding that the original Table, plus the procedures set out in the statute, provide an "intelligible principle" that cabins the Secretary's discretion. 195 F.3d at 1314 (App. 23a-24a).

Regarding the off-the-Table claim, the court, citing this Court's recent decision in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), held that the special master was correct to analyze the testimony of Petitioner's expert according to the *Daubert* factors and that he did not abuse his discretion in entirely disregarding that testimony. 195 F.3d at 1316 (App. 27a). In endorsing the special master's decision, the majority did not address whether the Compensation Program contained any special standards adopted by Congress that should have tempered his full-blown *Daubert* analysis.

In dissent, Judge Plager dismissed as "little more than a transparent attempt to find a verbal formula for disguising the reality of what transpired" the majority's reasoning that the Secretary's Table does not *really* amend the Compensation Program. *Id.* at 1319 (Plager, J., dissenting) (App. 35a-36a). Judge Plager accordingly concluded that the revision of the statutory Table by the Secretary was a violation of the Presentment Clause and would have vacated the decision below, remanding the case to the special master to consider Julie Terran's claim under the original Table. *Id.* at 1321 (Plager, J., dissenting) (App. 40a).

Petitioner timely filed a petition for rehearing and petition for rehearing *en banc*, which was denied on February 2, 2000. Petitioner's motion to recall and stay the mandate was granted on March 6, 2000.

REASONS FOR GRANTING THE WRIT

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S PRECEDENTS REGARDING THE CONSTITUTIONAL CONSTRAINTS ON DELEGATIONS OF RULEMAKING AUTHORITY.

A. The Compensation Program Violates the Presentment Clause.

In upholding the Secretary's power under section 300aa-14(c) to change the Table originally enacted by Congress, the Federal Circuit effectively circumvented the bedrock constitutional principle recently reiterated by this Court, that there is but a "single" method of making law, and that is the " 'finely wrought and exhaustively considered, procedure' " set out in the Presentment Clause of Article I. *Clinton*, 524 U.S. at 439-40 (quoting *INS v. Chadha*, 462 U.S. 919, 951 (1983)). It is elementary that, under our system of separated powers, legislation must be passed by both houses of Congress and presented to and signed by the President. *See* U.S. CONST. art. I, §§ 1, 7. Moreover, "[a]mendment and repeal of statutes, no less than enactment, must conform with Art. I." *Chadha*, 462 U.S. at 954.

The authority granted the Secretary under the Act, to "promulgate regulations to modify . . . the Vaccine Injury Table" by "add[ing] to, or delet[ing] from" the list of injuries for which compensation may be paid or by "chang[ing] the time periods" during which these symptoms must occur, clearly purports to empower the Secretary to amend a statute via rulemaking, and therefore violates the Presentment Clause. The panel majority's effort to deny that this is so was quite appropriately labeled by Judge Plager in dissent as an exercise in "verbal obfuscation." 195 F.3d at 1320 (Plager, J., dissenting) (App. 37a).

The majority below reasoned that the Table had not been amended or repealed because the Secretary's Table amounts to a regulation co-existing with the original

Table, which continues to apply to all petitions filed before the Secretary's Table was promulgated. *See id.* at 1315 (App. 25a-26a). Yet it cannot be denied that the power to revise the Table is the power to alter the substantive rights of those benefiting from the statute. Indeed, the Secretary has exercised that power to the specific detriment of Petitioner Julie Terran. As Judge Plager noted, the Secretary has "deleted a provision which, but for the deletion, would be available for the benefit of persons like Terran." *Id.* at 1320 (Plager, J., dissenting) (App. 37a). Her injuries would have been presumptively compensable under the original Table; under the Secretary's Table and modified QAIs, they are not. This power to alter legal rights created by statute is unquestionably the power of legislative amendment. *See Chadha*, 462 U.S. at 952 (House's action was "essentially legislative in purpose and effect" where it "had the purpose and effect of altering the legal rights, duties and relations of persons . . . outside the Legislative Branch"); *cf. Clinton*, 524 U.S. at 440-41 (citing fact that, "by canceling the items at issue in these cases, the President made them entirely inoperative *as to appellees*" (emphasis added) to refute argument that exercise of the line-item veto would "not effect a 'repeal' " of that provision).

Furthermore, the notion that the Secretary does not truly amend the statute because the text of the original Table is not wiped off the statute books is nonsense. By that logic, whenever Congress supersedes a statutory provision by enacting a new provision without explicitly repealing the old one or making the new provision retroactive, there has been no amendment of the law. As Judge Plager pointed out, "it is almost invariably the case that [when Congress amends a law], the provisions of the original statute remain in effect for all cases arising prior to the effective date of the amendment, and that the changed requirements apply only prospectively, to newly-arising matters." *See* 195 F.3d at 1320 (Plager, J.,

dissenting) (App. 37a). Under the panel majority's idea of lawmaking, then, Congress almost never amends statutes.

To be sure, the exercise of true rulemaking authority – the power to "mak[e] rules to fill any gap left, implicitly or explicitly, by Congress," *Morton v. Ruiz*, 415 U.S. 199, 231 (1974) – would not be subject to the procedures of the Presentment Clause. But here Congress itself enacted the initial Table in a statute rather than leaving promulgation of the Table to the Secretary in the first instance. The Secretary's Table does not by any interpretation "fill gaps" in the original Table; it changes what is already there, and so changes the scope of the Compensation Program as originally enacted by Congress, altering the rights Congress originally gave to children injured by vaccines. The character of such an action, regardless of its label as rulemaking, is clearly a legislative amendment and is therefore subject to the constraints of Article I. *See Metropolitan Washington Airports Auth. v. Citizens for the Abatement of Aircraft Noise*, 501 U.S. 252, 267 (1991) (" 'separation-of-powers analysis does not turn on the labeling of an activity' ") (quoting *Mistretta v. United States*, 488 U.S. 361, 393 (1989)); *Chadha*, 462 U.S. at 952 (whether an action is "an exercise of legislative power depends not on [its] form").

Nor can Congress's grant of legislative amendment power to the Secretary be considered legislation in the contingency as the majority below held, relying on this Court's decision in *Field v. Clark*, 143 U.S. 649 (1892). In *Field*, this Court upheld the President's authority under the Tariff Act to suspend certain statutory tariffs if other nations imposed on United States imports duties that the President "deem[ed] to be reciprocally unequal and unreasonable." *Id.* Focusing on the President's lack of discretion whether to suspend tariffs and the requirement that he do so upon the occurrence of a specific contingency, the Court held that "[l]egislative power was exercised when Congress declared that the suspension should take effect upon a named contingency," and that the

President was left with only the power to execute the law enacted by Congress. *Id.* at 693.

By contrast, section 300aa-14(c) does not direct the Secretary to take action upon the occurrence of a specific contingency, but grants her the power to alter the Table without awaiting any statutory trigger. The procedural prerequisites to Table amendment under section 300aa-14(c) are not a contingency diminishing the legislative character of the Secretary's amendments. To be mere execution of a previous legislative judgment by Congress, an action must be contingent on some event or condition *external* to the executive, not on something wholly within the executive's control, such as the decision to conduct a rulemaking.[8]

The First Circuit clearly understood the true character of the Secretary's power in a recent case seeking review of the regulations changing the Table. There, the First Circuit observed, "In crafting the Act, Congress delegated unusually great authority to the Secretary, including *the power to rewrite the statute* by updating one of its hallmark provisions." *O'Connell*, 79 F.3d at 180 (emphasis added). Though the First Circuit recognized that this was a power "to amend the statutorily enacted Table by way of administrative rulemaking," *id.* at 173, and so noted that "the Act may raise questions under the Presentment Clause," the issue was not raised by the parties and the court did not address it. *Id.* at 173 n.2.

In this case, the question has squarely been raised, and the Federal Circuit's answer conflicts with this Court's precedents, most notably its recent decision in *Clinton v. New York*. Indeed, the action of the Secretary in amending the Table is more egregious from a constitutional perspective than the line-item veto struck down in

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[8] The circuit majority's comparison of section 300aa-14(c) to "sunset" provisions is equally mistaken; sunset provisions are merely a subset of contingent legislation in that they direct the President to take a particular action (cessation of statutory enforcement) upon the passage of a statutorily specified date.

Clinton. At issue in *Clinton* was the President's "unilateral power *to change the text of [a] duly enacted statute[ ],*" 524 U.S. at 447 (emphasis added), but that change could only effect a cancellation of existing law, not replace existing law with new provisions devised by the President.[9]

Review is warranted not only because the constitutional vice in the regime established by the Act so dramatically affects the operation of the Compensation Program, but also because the separation of legislative and executive power achieved by the procedures of the Presentment Clause is so fundamental to our constitutional order. "The procedures governing the enactment of statutes set forth in the text of Article I were the product of the great debates and compromises that produced the Constitution itself." *Id.* at 439. Since the Founding, these procedures have been recognized as the bulwark protecting all other constitutional liberties.[10] Moreover, they create a more "effective and accountable" government in

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[9] For this reason, the power given to the Secretary by the Vaccine Act could not be seen as some variation of an otherwise unobjectionable power. *See Clinton*, 524 U.S. at 473 (Scalia, J., dissenting). Again, unlike a presidential power to elect not to give a provision legal effect, which would "leav[e] the statutes, as they are literally written, intact," *id.* (Breyer, J., dissenting), the Vaccine Act permits the Secretary not only to cancel or nullify legal provisions, but to create new substantive provisions in their place.

[10] *See, e.g., Clinton*, 524 U.S. at 450 (Kennedy, J., concurring) ("Liberty is always at stake when one or more of the branches seek to transgress the separation of powers."); *Metropolitan Washington Airports Auth.*, 501 U.S. at 272 ("The ultimate purpose of this separation of powers is to protect the liberty and security of the governed."); *Mistretta v. United States*, 488 U.S. 361, 380 (1989) (Separation of powers is "essential to the preservation of liberty."); *Loving v. United States*, 517 U.S. 748, 756 (1996) ("Even before the birth of this country, separation of powers was known to be a defense against tyranny."); *Clinton v. Jones*, 520 U.S. 681, 699 (1997) (quoting *Buckley v. Valeo*, 424 U.S. 1, 122 (1997)) (Separation of powers is a " 'self-executing

which lawmaking is assigned to the "branch most capable of responsive and deliberative lawmaking." *Loving v. United States*, 517 U.S. 748, 757-58 (1996). As recently as *Clinton*, this Court found the formal integrity of the separation of powers so crucial that it held it alone sufficient reason to invalidate the line-item veto provision at issue there. *See* 524 U.S. at 448 ("[O]ur decision rests on the narrow ground that the procedures authorized by the Line Item Veto Act are not authorized by the Constitution."). The Federal Circuit's decision in this case stands in stark conflict with this body of the Court's jurisprudence.

B. The Compensation Program Violates the Nondelegation Doctrine.

Even if the Compensation Program were viewed as passing muster under the Presentment Clause, we believe it would still be constitutionally infirm because the power given to the Secretary violates the nondelegation doctrine. We make this claim fully cognizant of the paradox that has burdened this doctrine: the nondelegation principle is, like the separation of powers, at the heart of our government's constitutional architecture,[11] but the standards for judicial application of the doctrine, as they have evolved in this Court's precedents, have rendered the doctrine almost nonjusticiable.[12] But it is for this very reason that we call the Court's attention to this doctrine as a basis for review here. Even under this Court's lenient

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safeguard against the encroachment or aggrandizement of one branch at the expense of the other.' ").

[11] *See J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 406 (1928); *Panama Refining Co. v. Ryan*, 293 U.S. 388, 430 (1935); *Field*, 143 U.S. at 692; *Mistretta*, 488 U.S. at 371. *See also* DAVID SCHOENBROD, POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION 107-34, 155-64 (1993).

[12] *Mistretta*, 488 U.S. at 372 (quoting *J.W. Hampton*, 276 U.S. at 406), 415 (Scalia, J., dissenting).

application of the nondelegation doctrine, the changes the Secretary made in the Table as originally enacted by Congress unmistakably show that the Secretary is the beneficiary of an "uncanalized delegation[ ] of legislative power." *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 675 (1980) (Rehnquist, J., concurring).

Though the Federal Circuit below acknowledged that "the Secretary could in theory delete all entries in the Table or, conversely, sweep in all possible illnesses or conditions," 195 F.3d at 1315 (App. 23a-24a), the Court nevertheless held that the Secretary's power was sufficiently constrained because the Act "establishes a broad program to study and reduce the risk of childhood vaccines" and Congress "clearly intended the Secretary to be guided by the findings from such studies when she decides to promulgate regulations to revise the injury table." *Id.* We believe this conclusion is wrong, and that the First Circuit, in contrast, got it exactly right when it observed that "[t]he only explicit constraints on the Secretary are procedural." *O'Connell*, 79 F.3d at 181. The aspects of the statute on which the Federal Circuit relied simply do not include any substantive congressional policy judgment with which the Secretary's actions must conform. *Cf. Industrial Union Dep't*, 448 U.S. at 683 (Rehnquist, J., concurring).

But to engage the nondelegation analysis at this level of generality is to miss the real nondelegation issue involved here. As we have described above, Congress clearly did expect that advances in scientific knowledge would "provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary . . . may propose to revise the Table." 60 Fed. Reg. 7679 (quoting House Report at 18). As a result of the surveys of scientific literature commissioned by the Vaccine Act, our understanding of the relationships between vaccine administrations and subsequent injuries could advance, to be sure, but would logically still yield judgments of three types: a judgment that science has clearly established a causal connection

between vaccine administration and certain injuries; a judgment that science has clearly established that there is no causal connection between vaccine administration and certain other injuries; and a judgment that the state of scientific knowledge has failed to establish whether or not any causal connection exists between vaccine administration and a third group of injuries.

Even giving the benefit of the doubt to the argument that the Secretary's mandated review of scientific studies provides an intelligible principle to guide the Secretary's discretion, that guidance can only come if the studies result in one of the first two kinds of these judgments. That is, when science says, "Yes, the vaccine causes this injury," or "No, the vaccine does not cause this injury," the Secretary's marching orders are arguably clear: she should amend the Table accordingly. Where science still does not have sufficient evidence to reach one of these conclusions, however, the great "we do not know" from the scientific community can by no stretch of logic guide the Secretary's discretion as to how to change the Table, if at all.

Simply put, the judgment as to whether to provide compensation to putative vaccine victims where science is uncertain about causation is not a question of science, but of pure policy: is compensating these people the right thing to do? And whether such a course is "right" can be shaped by a host of factors and judgments not addressed in the scientific literature.

The judgment Congress made in the Compensation Program is unmistakable. Where causation is uncertain, Congress chose to compensate a victim. As the House Energy and Commerce Committee explained:

> The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related . . . .

> Until such time [as "more definitive information" about causation is available], . . . the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

House Report at 18.

Even the Federal Circuit below recognized that the original Table swept more broadly because of uncertainty concerning the extent of causation and the desire to avoid any delay in implementing the Compensation Program. 195 F.3d at 1308 (App. 7a-8a). And Congress's recognition of the continuing limits on our knowledge of causation – and its choice to give claimants the benefit of the doubt – similarly are evident throughout the fabric of the statute. *See, e.g.*, 42 U.S.C. § 300aa-13(a)(2)(A) (App. 137a) (precluding the Secretary from rebutting a claimant's prima facie case by pointing to an "idiopathic," *i.e.*, unknown, factor).[13]

The Secretary's Table, by contrast, proceeds from a diametrically different policy perspective: where causation of an injury by a vaccine is uncertain – that is, neither proved or disproved – the claimants should not receive compensation under the Table. 60 Fed. Reg. 7681. Thus, the Secretary removed from the Table residual seizure disorder because "the 1991 IOM report concluded that no causal relationship can be proven between DPT and afebrile seizures." 60 Fed. Reg. 7690. Similarly, the Secretary radically limited the definition of encephalopathy to only its acute form because the IOM concluded

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[13] The Secretary herself described this provision as "requir[ing] that the claimant receive the benefit of the doubt on the issue of causation, even though it may be unlikely that the vaccine actually caused the injury." Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, *Shalala v. Whitecotton*, 514 U.S. 268 (1995) (No. 94-372) ("*Whitecotton* Cert. Petition"), at 17.

that "the evidence remains insufficient to indicate the presence or absence of a causal relation between DPT and chronic nervous system dysfunction under any other circumstances." 60 Fed. Reg. 7683 (quoting IOM Report Executive Summary).

In making a choice radically different from that made by Congress – to exclude children suffering from these injuries from the core benefit of the Compensation Program where evidence of causation was uncertain – the Secretary's dicretion was guided by nothing in the statute and nothing in the scientific literature[14] – in short, by nothing but the Secretary's own policy preferences.

Although the Court's nondelegation jurisprudence has been extremely forgiving, it does require some substantive principle, however modest or attenuated, that can be said to cabin administrative discretion.[15] No such

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[14] Indeed, with respect to the removal of residual seizure disorder from the Table, stating that the Secretary acted in the face of scientific uncertainty is too generous. The IOM Report, on which the Secretary relied, depended upon only one systematic study, the NCES. 60 Fed. Reg. 7685. And the NCES studied *only* those children "who experienced only febrile seizures." 60 Fed. Reg. 7684. Hence, the Secretary excluded from the Compensation Program children suffering from afebrile seizures, like Julie Terran, based on no systematic scientific study.

[15] *See, e.g., National Broad. Co., Inc. v. United States*, 319 U.S. 190, 214-25 (1943) (executive discretion curbed by requirement that officer "shall" act under certain circumstances and by elaboration of specific policy goals); *Yakus v. United States*, 321 U.S. 414, 420-21 (1944) (Statute outlined "when" Administrator should act, made a detailed policy statement to which he was required to defer, and set out factors to which he must give "due consideration" in setting prices.); *United States v. Rock Royal Coop., Inc.*, 307 U.S. 533, 547, 574-77 (1939) (Secretary's power to set prices upheld because it was limited to specified commodities, Congress had provided a comprehensive policy statement, and any price-setting order must contain "one or more" of the provisions listed by Congress).

principle exists here, freeing the Secretary to exercise her policy predilections at a real human cost.

In sum, review of this case is also warranted because of the significant, albeit rare, violation of the nondelegation doctrine that has corrupted the Compensation Program, at Julie Terran's expense.[16]

II. THE DECISION BELOW MANIFESTS THE CONTINUING CONFUSION OF THE LOWER COURTS CONCERNING THE STANDARD OF PROOF REQUIRED UNDER THE COMPENSATION PROGRAM, AN ISSUE OF CENTRAL IMPORTANCE TO THE OPERATION OF THE STATUTE.

The special master's decision rejecting Petitioner's off-the-Table claim is the most recent manifestation of an intra-circuit conflict over the legal standard governing the proof needed to prevail in such a "causation-in-fact" case. The decision below thus continues a judicial regime of profound uncertainty and disparate results that undermines the operation of a key feature of the Compensation Program as designed by Congress. Moreover, since the Court of Federal Claims is the only court to which claims under the Compensation Program may be made, and the Federal Circuit, in turn, is the exclusive appellate forum for that court, no conflict among the Circuits is possible. Thus, this intra-circuit conflict underscores the vital importance of this Court's review now.

Though much of the special master's analysis relating to Petitioner's off-the-Table case focused on the application of the *Daubert* principles, the special master's error applying *Daubert* is actually a secondary matter, flowing from a more basic flaw at work in the special master's reasoning. In rejecting Petitioner's off-the-Table claim, the

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[16] Indeed, given the practical problems with the "intelligible principle" test, the Court may wish to consider whether other, more judicially manageable tests, should be adopted. *Cf.* SCHOENBROD, *supra* note 11, at 180-91.

special master grounded his analysis on the following proposition: "The burden [for an off-the-Table case] rests on the petitioner to show that the vaccination in question more likely than not caused the specific injury, *under the same standards which apply in traditional tort litigation*, in which the same 'preponderance of the evidence' standard applies." App. 75a (emphasis in original).

The special master cited several Federal Circuit precedents for his conclusion that the "traditional causation in fact standard" used in tort cases outside the Compensation Program is the standard for off-the-Table cases. *See, e.g., Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). Under this line of cases, the "Act relaxes proof of causation for injuries satisfying the Table . . . , but does not relax proof of causation in fact." *Id.* at 370. *See also Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Consistent with this notion that the traditional tort standard applies, such opinions hold that the preponderance of the evidence that must support a claim requires that "[a] reputable medical or scientific explanation must support this logical sequence of cause and effect [between a vaccine and an injury]." *Id.* It was from this springboard that the special master concluded that, because the explanation of *how* the vaccine caused Petitioner's injuries offered by her expert was not broadly accepted by the medical community, the simpler contention that the DPT vaccine had *caused* Petitioner's injuries was also unreliable. App. 83a-84a. It was only by such reasoning – that a claimant must offer a reliable medical explanation for causation – that the special master could conclude that Petitioner had failed to establish her claim by a preponderance of the evidence even though he also recognized that no factor unrelated to the administration of the vaccine had caused her injuries. App. 89a.

Yet a separate line of Federal Circuit precedent implicitly takes a decidedly different view, reading the statute, correctly we believe, to relax proof of causation in fact when a claimant is proceeding under the Compensation

Program. This certainly is a logical conclusion: why have an off-the-Table scheme at all if it is essentially the same as a state tort action? More importantly, the conclusion follows more faithfully from the text and structure of the statute itself.

To secure an award under the Compensation Program off-the-Table, causation must be demonstrated by a preponderance of the evidence, 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(II), -13(a)(1)(A) (App. 125a-136a), *and* there must not be a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B) (App. 136a). Such factors unrelated to the vaccine may not include "idiopathic," hypothetical, or unexplained causes. 42 U.S.C. § 300aa-13(a)(2)(A). Federal Circuit precedents that depart from the cases on which the special master relied recognize that the effective burden of proof in an off-the-Table case results from the interplay of these two provisions. As the Federal Circuit succinctly put it in *Bunting v. Secretary of HHS*, 931 F.2d at 872, "The lack of evidence of other possible causes is also a factor to be weighed in determining causation due to the vaccine."

Indeed, it is the Secretary herself who has most cogently explained this second prong of the standard of proof, particularly the exclusion of idiopathic factors unrelated to the vaccine. In her Petition for a Writ of Certiorari in the *Whitecotton* case, she explained to this Court:

> The Act precludes the Secretary from relying on an "idiopathic" factor to rebut a prima facie case, and medical dictionaries uniformly define "idiopathic" as "of unknown cause." The Secretary therefore cannot attempt to defeat a prima facie case by relying on a statement from an expert such as "I have no idea what caused the injury, but it could not have been the vaccine." That statutory protection for the claimant is important. There is a considerable body of medical opinion that serious adverse neurological events following vaccinations are exceedingly rare. Because the Act precludes reliance on

> "idiopathic" or "unknown" factors to rebut a prima facie case, the Secretary could not rely on that body of medical opinion alone to rebut a prima facie case. The Secretary instead must point to some identifiable condition as an explanation for a claimant's injuries. When the Secretary is unable to do that, *the Act requires that the claimant receive the benefit of the doubt on the issue of causation*, even though it may be unlikely that the vaccine actually caused the injury.

Whitecotton Cert. Petition at 17 (emphasis added; internal citations omitted). *See also* Brief for the Petitioner, *Shalala v. Whitecotton*, 514 U.S. 268 (1995) (No. 94-372), at 30-33.

This statutory "benefit of the doubt," as the Secretary put it, does, in the view of some Federal Circuit panels, translate into a more "relaxed" standard of proof than the courts below applied in this case. For example, in *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548-49 (Fed. Cir. 1994), the court explained, "The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *See also Bunting*, 931 F.2d at 873 (noting that the "standard of proof required by the Act is simple preponderance of evidence; not scientific certainty," and that the findings of the court do not have to "meet the standards of the laboratorian") (citation omitted).

The significance of these two divergent strains of Federal Circuit precedents is acutely apparent in this case. If, for example, the special master had followed *Knudsen* or *Bunting* instead of *Strother* or *Grant*, it is very likely that Petitioner's claim would not have been denied because all the evidence indicated a causal link between Julie Terran's injuries and the DPT vaccination. The special master concluded Petitioner had not established causation because he found her expert's explanation of the *mechanism* by which those injuries were caused to be unreliable. This kind of reasoning, while reflecting the analysis in *Grant* noted above, was explicitly rejected by the Federal Circuit in *Knudsen*:

> [T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program . . . .
>
> . . . .
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DPT and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others . . . . The special masters are not "diagnosing" vaccine-related injuries.

Knudsen, 35 F.3d at 549.

In short, the Federal Circuit's decision affirming the special master conflicts with other precedents of the Federal Circuit on an issue that is central to the operation of the Compensation Program, and so warrants review. *See Dickinson v. Petroleum Conversion Corp.* 338 U.S. 507, 508 (1950) (certiorari granted because of an intracircuit conflict); *John Hancock Mut. Life Ins. Co. v. Bartels*, 308 U.S. 180, 181 (1938) (certiorari granted because of the importance of the question and intracircuit conflict).

CONCLUSION

For the reasons stated above, this Court should grant this petition for a writ of certiorari.

Respectfully submitted,

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April 28, 2000

United States Court of Appeals for the Federal Circuit

98-5161

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Andrew W. Dodd, of Torrance, California, argued for petitioner-appellant.

Claudia G. Gangi, Trial Attorney, Torts Branch, Civil Division, Department of Justice, of Washington, DC, argued for respondent-appellee. With her on the brief were *Helene M. Goldberg*, Director and *John Lodge Euler*, Deputy Director.

Appealed from: United States Court of Federal Claims

Judge Moody R. Tidwell

United States Court of Appeals for the Federal Circuit

98-5161

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

DECIDED: October 27, 1999

Before PLAGER, LOURIE, and CLEVENGER, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* CLEVENGER. Dissenting opinion filed by *Circuit Judge* PLAGER.

CLEVENGER, *Circuit Judge.*

Michele Terran appeals from the judgment by the United States Court of Federal Claims sustaining the Special Master's decision to deny compensation to Julie F. Terran under the National Child Vaccine Injury Act of 1986 (the "Vaccine Act" or "Act"). *See Terran v. Secretary of Health & Human Services,* No. 95-451V (Fed. Cl. July 10, 1998). Terran argues that the Vaccine Injury Table applied by the Special Master to her claim is invalid because the statutory scheme pursuant to which it was created is unconstitutional, and also that the Court of Federal Claims erred both legally and factually in sustaining the Special Master's ruling. We hold, however, that the Vaccine Act does not violate separation of powers principles, and that the Court of Federal Claims committed no reversible error. We therefore affirm.

I

This appeal raises three issues: (i) whether the Court of Federal Claims has jurisdiction to adjudicate constitutional challenges to the validity of the current Vaccine Injury Table, which was promulgated by the Secretary pursuant to 42 U.S.C. § 300aa-14(c) and which became effective on March 10, 1995 (the "1995 Table"); (ii) whether the section of the Vaccine Act that authorizes the Secretary to create the 1995 Table, *see* 42 U.S.C.

§ 300aa-14(c) (1994), violates separation of powers principles found in the Constitution; and (iii) whether the Court of Federal Claims erred in sustaining the Special Master's decision to deny Julie compensation under the Vaccine Act.

A

The relevant facts are not in dispute. Julie Terran was born on February 10, 1992, in Phoenix, Arizona, and was discharged in good health from the hospital the next day. Julie received her first diphtheria-pertussis-tetanus ("DPT") vaccination when she was two months old, and her second DPT vaccination when she was three and one-half months old. On August 10, 1992, when Julie was six months old, she received her third DPT vaccination. Julie received her fourth DPT vaccination on September 22, 1993. All of the vaccinations were given by Dr. Gary Berebitsky, Julie's pediatrician, at her well-baby care checkup examinations. The first three DPT vaccines utilized whole cell pertussis bacteria, whereas the fourth was an acellular DPT vaccine. Julie's third vaccination, which occurred on August 10, 1992, is the basis for this dispute.

On August 11, 1992, the day after her third DPT vaccination, Julie experienced a seizure lasting approximately seven seconds which caused one of her arms to become stiff. The next day, August 12, Julie suffered four afebrile seizures, each lasting roughly one minute in length. Immediately after the seizures, Julie was rushed by ambulance to Phoenix Children's Hospital, where she was admitted. On August 13, in the presence of hospital

personnel, Julie suffered another seizure lasting approximately five and one-half minutes. Hospital personnel then administered the anti-convulsant drug Phenobarbital to Julie. In the seven days following Julie's third DPT vaccination, she experienced a total of approximately twelve minutes of seizure activity. On September 12, roughly one month after the vaccination in question, Julie suffered a seizure lasting 50 minutes even though she was on Phenobarbital at the time. Julie's seizures continue to this day.

On September 13, 1993, Dr. Berebitsky noted that Julie was "well appearing" and "neurologically intact." However, in November 1993, he noted a problem with Julie's neurological condition, indicating that she scored a borderline passing grade on the Denver Developmental Screening Test. Julie is currently mentally retarded.

Julie also had a meningocele lump removed from her skull as a young child. Prior to her third DPT vaccination, Julie's doctors conducted several tests to determine whether she suffered any permanent brain damage as a result of the lump. These tests concluded that she had no brain abnormalities. An MRI scan conducted on May 18, 1992, showed that Julie had normal brain structure, and a test showed that there was no cancer in the removed lump. A certified pediatric neurosurgeon conducted a follow-up on Julie's surgery and found her neurological condition to be unremarkable except for moderate strabismus. Two MRI's conducted after Julie's third vaccination showed that she had no structural pathology in her brain. In connection with Terran's claim for compensation under the Vaccine Act, the Government requested

that Julie undergo two separate genetic workups, both of which showed normal results.

B

Childhood vaccinations, though an important part of the public health program, are not without risk. Because vaccines often contain either killed bacteria or live but weakened viruses, they can cause serious adverse effects. *See O'Connell v. Shalala*, 79 F.3d 170, 172 (1st Cir. 1996) (citing Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines 1 (1991)). Despite the relatively rare occurrence of such problems, Congress became concerned that tort liability and related costs might drive up the prices of vaccines and discourage vaccine manufacturers from staying in this market, and that normal tort litigation might leave many sufferers of vaccine-caused injuries uncompensated. *See* H. R. Rep. No. 99-908, at 1, 4, 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344, 6345, 6347-48; *see also O'Connell*, 79 F.3d at 172-73.

Accordingly, in 1986, Congress passed the National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, 1986 U.S.C.C.A.N. (100 Stat.) 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (1994)), which established a program administered by the Secretary of Health and Human Services ("Secretary") to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-1 (1994). As part of this program, Congress established a Vaccine Injury Compensation Program through which claimants could petition to receive compensation for vaccine-

related injuries or death. *See id.* § 300aa-10(a). To receive compensation, a claimant must petition the Court of Federal Claims and demonstrate by a preponderance of the evidence either that (i) the vaccinated child suffered an injury listed on a table, or a complication or "sequela" thereof; or (ii) that the vaccine caused or significantly aggravated the child's injury or condition. *See id.* §§ 300aa-11, -13 to -14; 42 C.F.R. § 100.3 (1996). Thus, the Vaccine Act provides two possible ways for a claimant to receive compensation: first, by showing that she suffered a "table injury," or second, by proving causation in fact.[1] The Vaccine Act establishes an Office of Special Masters within the United States Court of Federal Claims to decide petitions for compensation, provides for review of a Special Master's decision by the Court of Federal Claims, and allows appeal of the Court of Federal Claims's rulings to this court. *See* 42 U.S.C. § 300aa-12 (1994).

To aid the Vaccine Program's goal of providing efficient compensation for vaccine injuries, Congress provided, in the form of a table, a list of vaccines, a parallel list of adverse medical conditions commonly associated with the use of each vaccine, and, for certain medical

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[1] However, the Vaccine Act does not preclude traditional tort remedies. A person claiming injury due to a vaccine is required to seek redress first through the Vaccine Act, but if she is not satisfied with the result, she may reject the judgment and litigate her claim in federal or state courts, subject to certain limitations imposed by the Vaccine Act. *See* 42 U.S.C. §§ 300aa-11(a), 300aa-21 (1994); *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2-3 (1st Cir. 1994) (discussing the relation between the Vaccine Act and the traditional tort system).

conditions, a time period in which the first symptoms should become apparent following vaccination. *See id.* § 300aa-14(a). These listings comprise the initial Vaccine Injury Table (the "Initial Table"), and are to be read in conjunction with a separate subsection, the "Qualifications and aids to interpretation" (the "QAIs"), that provides explanations and definitions for terms used in the Initial Table. *Id.* § 300aa-14(b). To demonstrate a table injury, a claimant must prove that within the prescribed time period following a vaccination, she suffered one of the disorders set forth on the Vaccine Injury Table corresponding to the vaccine administered. If she cannot make this showing, she must instead prove causation in fact. For example, with respect to a DPT vaccine, the Initial Table grants recovery if the claimant suffers, *inter alia*, a first symptom of, or a first manifestation of onset of, "residual seizure disorder" or "encephalopathy" within three days of receiving the vaccine. *See id.* The QAIs define "encephalopathy" to mean "any significant acquired abnormality of, or injury to, or impairment of function of the brain," and set forth certain symptoms or manifestations of an encephalopathy. *Id.* § 300aa-14(b)(3)(A).

Congress included the Initial Table in the Vaccine Act legislation, rather than delegating the creation of the first injury table to the Secretary, because it was concerned that the administrative process would significantly delay the implementation of the Vaccine Compensation Program. *See* Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce, 98th Cong. 210-11 (1984) (letter from Martin H. Smith, Vice President, American Academy of Pediatrics to Representative Henry

A. Waxman). Congress intended the Secretary to revise and update the Initial Table with more accurate information that would become available as a result of the research on vaccine injuries mandated by the Vaccine Act. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-81 (requiring the Secretary to make findings on the accuracy of the Initial Table with respect to, *inter alia*, pertussis vaccines and to propose regulations to modify the Initial Table accordingly); H.R.Rep. No. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Thus, the Vaccine Act gives the Secretary the express power to promulgate regulations that modify the Table by adding to, or deleting from, the list of compensable disorders and by revising the time periods contained in the Table. *See* 42 U.S.C. § 300aa-14(c)(3) (1994). The Vaccine Act requires the Secretary to make such modifications pursuant to notice and comment rulemaking, and to provide at least 180 days for public comment and an opportunity for a public hearing. *See id.* § 300aa-14(c)(1). In addition, the Act provides that if the Initial Table is modified, the original QAIs cease to apply unless the modified Table expressly states that they remain valid. *See id.* § 300aa-14(c)(4). In February 1995, the Secretary promulgated regulations creating the current Vaccine Injury Table (the "1995 Table") and associated new QAIs, which became effective on March 10, 1995. *See* 42 C.F.R. § 100.3 (1996). As relevant to this case, the 1995 Table and associated QAIs deleted residual seizure disorder ("RSD") from the list of compensable table injuries related to DPT vaccine and significantly narrowed the definition of "encephalopathy." The 1995 Table and the modified QAIs

apply to all petitions filed on or after their effective date of March 10, 1995. *See* 42 U.S.C. § 300aa-14(c)(4) (1994).

C

Terran filed a petition for compensation with the Court of Federal Claims on July 12, 1995. The petition alleged that Julie's third DPT vaccination, administered on August 10, 1992, caused Julie to suffer both RSD and encephalopathy. Because the 1995 Table does not list RSD as a compensable injury associated with DPT vaccine, the Special Master concluded that Terran must establish causation in fact to prevail on this count. With respect to encephalopathy, Terran conceded that Julie's disorder did not meet the definition of an encephalopathy as set forth in the revised QAIs, and the Special Master accordingly concluded that Terran could prevail only if she demonstrated causation in fact for this illness as well. *See Terran v. Secretary of Health & Human Servs.*, No. 95-451V, slip op. at 8-9 (Fed. Cl. (Special Master) Jan. 23, 1998). After examining the medical records and testimony, the Special Master determined that Terran failed to establish a *prima facie* case of causation in fact for either of Julie's conditions and denied compensation. *See id.* at 18.

Terran sought review of the Special Master's findings in the Court of Federal Claims. In her motion for review, Terran first alleged that the Vaccine Act is unconstitutional insofar as it authorizes the Secretary to modify the statutorily-enacted Initial Table found at 42 U.S.C. § 300aa-14(a) via administrative rulemaking. Second, Terran argued that even if the 1995 Table was valid, the Special Master erred in applying it to Julie's case and that

he improperly rejected her theory of causation in fact under *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579 (1993). The Court of Federal Claims held that it was without jurisdiction to consider Terran's constitutional challenge, and sustained the Special Master's decision in all respects. *See Terran*, No. 95-451V, slip op. at 5, 10. Terran then petitioned for review to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

II

We consider first the Court of Federal Claims's ruling that it does not have jurisdiction to consider appellant's constitutional challenge to the Vaccine Act. We review questions involving the jurisdiction of the Court of Federal Claims *de novo. See Widdoss v. Secretary of Health & Human Servs.*, 989 F.2d 1170, 1174 (Fed. Cir. 1993). Determining the jurisdiction of the Court of Federal Claims necessarily involves statutory interpretation, which we likewise review *de novo. See Munn v. Secretary of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1993); *Neher v. Secretary, Dept. of Health & Human Servs.*, 984 F.2d 1195, 1197-98 (Fed. Cir. 1993).

A

The Court of Federal Claims found that it lacked jurisdiction on two grounds. Reciting the well-known fact that it only has jurisdiction to hear claims against the Government for money damages, the court ruled that Terran's argument that the Vaccine Act violated the Presentment Clause of the Constitution, *see* U.S. Const. art. I,

§ 7, cl. 2, was not based on a "money mandating provision" of the Constitution, thereby depriving it of jurisdiction. *See Terran v. Secretary of Health & Human Servs.*, No. 95-451V, slip op. at 5 (Fed. Cl. July 10, 1998) (citing *Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980)).

It is well understood that the Court of Federal Claims, like all federal courts, is a court of limited jurisdiction. Its jurisdiction is defined by the Tucker Act, which gives that court authority to

> render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort.

28 U.S.C. § 1491(a)(1) (1994). The Supreme Court has interpreted this language to mean that a plaintiff who seeks redress in the Court of Federal Claims must present a claim for "actual, presently due money damages from the United States." *United States v. King*, 395 U.S. 1, 3 (1969); *see also United States v. Testan*, 424 U.S. 392, 400 (1976). Although the Tucker Act provides jurisdiction for damage suits against the United States Government, it is equally clear that the Tucker Act does not itself create a cause of action against the Government. Rather, a plaintiff seeking recovery against the Government in the Court of Federal Claims must point to a money-mandating constitutional provision, statute, regulation, or contract with the United States affording it a right to money damages. *See United States v. Mitchell*, 463 U.S. 206, 216-17 (1983); *Loveladies Harbor, Inc. v. United States*, 27 F.3d 1545, 1554

(Fed. Cir. 1994) (en banc); *United States v. Connolly*, 716 F.2d 882, 885 (Fed. Cir. 1983) (en banc).

We think that the Court of Federal Claims misconstrued the scope of its jurisdiction. The Presentment Clause of the Constitution states that before becoming law, a legislative act must be approved by both houses of Congress and must be presented to the President of the United States for approval. *See* U.S. Const. art. I, § 7, cl. 2. We agree that this constitutional provision neither explicitly nor implicitly obligates the federal Government to pay damages, and accordingly is not by itself actionable in the Court of Federal Claims. *Cf. Connolly*, 716 F.2d at 887 (holding that the First Amendment does not by itself give rise to a cause of action for damages); *Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (holding that claims based on the Fifth Amendment's Due Process and Equal Protection clauses do not give rise to jurisdiction under the Tucker Act); *Walton v. United States*, 213 Ct. Cl. 755, 757 (1977). When determining jurisdiction, however, we must look to the true nature of the underlying action. *See Katz v. Cisneros*, 16 F.3d 1204, 1207 (Fed. Cir. 1994); *Livingston v. Derwinski*, 959 F.2d 224, 225 (Fed. Cir. 1992). Here, Terran's claim for relief is based on the Vaccine Act and is a claim for money – that is, compensation under the Act. Therefore, the Vaccine Act is the "Act of Congress" which forms the basis of Terran's claim, and there is little dispute that such a claim is one for presently due money damages. Indeed, we note that the Vaccine Act itself gives jurisdiction to the Court of Federal Claims to determine whether Terran is entitled to compensation, independent of the Tucker Act. *See* 42 U.S.C. § 300aa-12(a) (1994).

Because jurisdiction is proper, the Court of Federal Claims had the power to address Terran's argument based on the Constitution. *See Beck v. Secretary*, 924 F.2d 1029, 1036 (Fed. Cir. 1991) ("It is, however, reasonable to infer that the [Vaccine] Act must confer on the Claims Court that power which is necessary to adjudicate the controversy before it."); *compare Connolly*, 716 F.2d at 887 (holding that the Court of Claims did not have jurisdiction over plaintiff's First Amendment claim of improper removal) *with Jackson v. United States*, 428 F.2d 844, 846 (Ct. Cl. 1970) (holding that the Court of Claims did have jurisdiction over plaintiff's statutory claim for back pay, including arguments based on the First Amendment). We are therefore convinced that Terran's claim for compensation under the Vaccine Act properly lies within the jurisdiction of the Court of Federal Claims, unless ousted on the second ground decided by the court.

B

The Court of Federal Claims also held that a provision in the Vaccine Act providing for immediate judicial review of rules promulgated under the Act precluded it from reviewing Terran's challenge to the validity of the 1995 Table. That statutory review provision states:

> A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

42 U.S.C. § 300aa-32 (1994). The Court of Federal Claims held that this provision requires a party challenging regulations promulgated under the Act to raise such challenges within 60 days if the factual basis for such a challenge existed at that time. *See Terran v. Secretary of Health & Human Servs.*, No. 95-451V, slip op. at 5 (Fed. Cl. July 10, 1998). Because Julie experienced seizures as early as 1992 and had a diagnosed neurological condition by November 1993, the court held that Terran could have challenged the 1995 Table in March 1995, when it was promulgated, and was barred from doing so now. *See id.*

Again, we disagree with the jurisdictional analysis by the Court of Federal Claims. The first and most important step when interpreting a statute is, of course, analyzing its text. It is significant that the language of section 300aa-32 conferring jurisdiction on federal appellate courts is permissive in nature – parties *may* file a petition for review of regulations promulgated under the Vaccine Act in the courts of appeals within 60 days of their enactment. The statutory language does not explicitly *require* a party to challenge regulations under the Vaccine Act within such time period and in such a forum. Therefore, we cannot say that Congress clearly intended to limit judicial review to the 60-day period. The language in section 300aa-32 thus differs from the mandatory language found in some other statutory review clauses. *See Eagle-Picher Indus. v. EPA*, 759 F.2d 905, 911 (D.C. Cir. 1985) (holding that a statutory provision of CERCLA clearly foreclosing later judicial review of matters that could have been raised in the ninety day statutory period bars a later challenge).

Nevertheless, we recognize that there are cases in which courts have held that statutory review provisions specifying a limited time period for challenging regulations in a particular forum preclude later challenges to those regulations. The District of Columbia Circuit, for example, has held that statutory time limits on review of agency rulemaking can foreclose subsequent challenges to those rules. *See, e.g., Eagle-Picher,* 759 F.2d at 911; *Natural Resources Defense Council v. NRC,* 666 F.2d 595, 601-03 (D.C. Cir. 1981). These cases, however, do not support the Government's broad contention that review of vaccine regulations is never proper after expiration of the 60-day statutory review period. In *Eagle-Picher,* for example, the statutory provision at issue was section 113(a) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 ("CERCLA") which, as already mentioned, specifically stated that agency rules had to be challenged within 90 days, and any matter which could have been raised in that time period was not subject to later judicial review. *See* 42 U.S.C. § 9613(a) (1982); *Eagle-Picher,* 759 F.2d at 911. More importantly, the case law provides several exceptions under which subsequent judicial review of a regulation would still be proper. *See Public Citizen v. NRC,* 901 F.2d 147, 152 & n.1 (D.C. Cir. 1990); *NLRB Union v. Federal Labor Relations Auth.,* 834 F.2d 191, 195-96 (D.C. Cir. 1987); *Eagle-Picher,* 759 F.2d at 913-14 & n.45; *Natural Resources Defense Council,* 666 F.2d at 602 & nn.47-49. One important exception is that when a party seeks to challenge a regulation on substantive grounds of invalidity, such as that the regulation was not authorized by legislation, review may still be had. *See Public Citizen,* 901 F.2d at 152 & n.1;

Natural Resources Defense Council, 666 F.2d at 602. This is especially true when the subsequent challenge occurs in an agency enforcement proceeding. *See NLRB Union*, 834 F.2d at 195-196 ("As applied to rules and regulations, the statutory time limit restricting judicial review of [agency] action is applicable only to cut off review directly from the order promulgating a rule. It does not foreclose subsequent examination of a rule where properly brought before this court for review of further [agency] action applying it.") (quoting *Functional Music, Inc. v. FCC*, 274 F.2d 543, 546 (D.C. Cir. 1958)); *see also Cronin v. FAA*, 73 F.3d 1126, 1131 n.3 (D.C. Cir. 1996) (stating that airline pilots could challenge the legality of an FAA regulation in subsequent enforcement actions against them).

Terran's claim in this case – that the 1995 Table is an invalid regulation because that section of the Vaccine Act authorizing its creation is unconstitutional – is a substantive challenge to the validity of the 1995 Table. In addition, the Special Master clearly applied the 1995 Table to Terran's claim for compensation in an adjudication, which in many ways is similar to the agency actions discussed in *NLRB Union* and *Functional Music*. Therefore, even if section 300aa-32 generally bars subsequent litigation over the validity of vaccine regulations, Terran falls within both well established exceptions identified above. We therefore conclude that 42 U.S.C. § 300aa-32 does not preclude the Court of Federal Claims from exercising jurisdiction over Terran's substantive challenge to the validity of the 1995 Table.

III

We turn next to the substance of Terran's constitutional challenge to the Vaccine Act. Terran raises two theories as to why 42 U.S.C. § 300aa-12(c), which authorizes the Secretary to promulgate a revised Vaccine Injury Table, is unconstitutional. First, Terran claims that section 300aa-12(c) authorizes the Secretary to amend part of a statute, namely the Vaccine Injury Table found in section 300aa-12(a), via administrative rulemaking, and therefore contravenes the Presentment Clause of the Constitution. *See* U.S. Const. art. I, § 7, cl. 2. Alternatively, Terran contends that the Vaccine Act effects an unconstitutional delegation of legislative authority to the Secretary.

A

The Presentment Clause requires, in relevant part, that "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it," U.S. Const. art. I, § 7, cl. 2. There is no dispute that the Secretary's actions here did not fulfill the bicameralism and presentment conditions required of legislative acts by the Presentment Clause; the only question, therefore, is whether the Presentment Clause applies to the Secretary's promulgation of the regulation establishing the 1995 Table.

The Presentment Clause is inapplicable to administrative rulemaking in general, of course, because rulemaking is by definition not a legislative act, but rather an exercise of executive function properly

entrusted to administrative agencies. *See, e.g., American Trucking Assns., Inc. v. United States*, 344 U.S. 298, 310-13 (1953). Nevertheless, because the Initial Table was made a part of the Vaccine Act, *see* 42 U.S.C. § 300aa-14(a) (1994), Terran insists that the Secretary's power to modify the Table effectively allows her to amend or repeal part of a statute, and thus violates the Presentment Clause. Terran argues that this result is dictated by the Supreme Court's decisions in *Clinton v. New York*, 524 U.S. 417 (1998), in which the Court held that the Line Item Veto Act violates the Presentment Clause, and *INS v. Chadha*, 462 U.S. 919, 954-59 (1983), in which the Court struck down a legislative veto provision in a statute.

The Constitution does not authorize members of the executive branch to enact, amend, or repeal statutes. *See Clinton*, 524 U.S. at 438. Instead, this legislative power is vested exclusively in Congress, and the exercise of such legislative power must follow the procedures set forth in the Constitution. *See Chadha*, 462 U.S. at 954 ("Amendment and repeal of statutes, no less than enactment, must conform with Art[icle] I."). The critical question in this case is therefore whether the Secretary's action in promulgating the 1995 Table should properly be understood as an amendment or a repeal of an existing law.

We are convinced that the Vaccine Act does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations as contemplated in the Act. First, as a formal matter, the Act does not in fact allow the Secretary to explicitly amend the Initial Table. Although we acknowledge that the statutory language in section 300aa-14(c) refers to the Secretary's ability "to modify"

and "to amend" the Vaccine Injury Table, 42 U.S.C. § 300aa-14(c)(1), (2) (1994), a closer reading of that section makes clear that when the Secretary acts pursuant to section 300aa-14(c), she does not change in any way the original injury table found in section 300aa-14(a), but rather promulgates an entirely new vaccine injury table. This new table applies only prospectively. *See* 42 U.S.C. § 300aa-14(c)(4) (1994). The Initial Table remains codified and unaltered, and continues to apply to all petitions filed before the revision. Therefore, the Initial Table is not amended.

Realizing this, Terran argues instead that the Act *effectively* allows the Secretary to amend the Initial Table. However, we are not persuaded that the regulatory regime established by the Vaccine Act raises concerns under the Presentment Clause. When it created the Vaccine Act, Congress realized that the Initial Table contained flaws. *See, e.g.*, H.R. Rep. No. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Congress therefore directed the Secretary to commission studies on the link between vaccines and injuries, and created a panel to oversee the collection of data on vaccine related injuries. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660 §§ 312-13, 100 Stat. 3755, 3779-82 (1986); 42 U.S.C. § 300aa-19 (1994). Congress directed the Secretary to revise the Initial Table based on the information obtained from such studies. *See, e.g.*, National Childhood Vaccine Injury Act of 1986, 100 Stat. at 3779-80. Congress therefore clearly intended that the Initial Table would cease to apply to newly filed petitions when the Secretary promulgated a revised injury table. *See id.* § 300aa-14(c)(4). This aspect of the Vaccine Act is similar to "sunset" provisions

that Congress routinely includes in legislation to specify the date on which a particular piece of legislation ceases to have effect. *See, e.g.*, 28 U.S.C.A. § 599 (West Supp. 1999) (specifying that Title 28, Chapter 40 of the United States Code – authorizing the appointment of independent counsels – ceases to be effective five years after the date of enactment of the Independent Counsel Reauthorization Act of 1994). Here, of course, the Vaccine Act does not specify a date certain on which the Initial Table becomes ineffective; instead, the Secretary's promulgation of a revised injury table triggers the ineffectiveness of the Initial Table. Because Congress itself decided to render the Initial Table ineffective upon the Secretary's action, this statutory design does not violate the Presentment Clause. *See Clinton*, 524 U.S. at 446 & n.40 (stating that the Supreme Court's power to "repeal" laws by promulgating rules of procedure for the lower federal courts does not run afoul of the Presentment Clause because "Congress itself made the decision to repeal prior rules upon the occurrence of a particular event – here, the promulgation of procedural rules by this Court").

The Supreme Court's recent decision in *Clinton v. New York* is not to the contrary. In holding the Line Item Veto Act unconstitutional in *Clinton*, the Court identified three factors distinguishing that statute from the one at issue in *Field v. Clark*, 143 U.S. 649 (1892), in which the Court upheld the constitutionality of the Tariff Act of 1890 that authorized the President to suspend legislatively-enacted import duty exemptions on certain goods whenever he felt that the exporting country was treating United States products unfairly. *See Clinton*, 524 U.S. at

442-43; Act of Oct. 1, 1809, § 3, 26 Stat. 612. First, the Court noted that the President's suspension power under the Tariff Act was contingent on conditions that did not exist when that law was passed, whereas the five-day time limit for canceling an appropriations line item under the Line Item Veto Act meant that the President's action was necessarily based on the same conditions contemplated by Congress. *See id.* at 443. In the Vaccine Act, as in the Tariff Act, Congress anticipated that the facts underlying its legislation might change in the future. *See, e.g.*, 42 U.S.C. § 300aa-19 (1994) (establishing the Advisory Commission on Childhood Vaccines and directing it to compile information relating to vaccine injury statistics), § 300aa-14(d) (1994) (requiring the Secretary to solicit comments from the Advisory Commission before promulgating a revised injury table). As a result, Congress intended the Secretary to promulgate revised injury tables when more accurate information linking vaccines to injuries became available. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-360, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-80.

Second, the *Clinton* Court noted that the Line Item Veto Act provided little constraint on the President's discretion to cancel a particular appropriation line item, whereas his discretion was much more channeled under the Tariff Act. *See Clinton*, 524 U.S. at 443-44. This factor also suggests that the delegation of power found in the Vaccine Act is proper. Although the Secretary ultimately has the discretion to either promulgate a revised table or not, Congress set forth detailed procedures and substantive considerations in the Vaccine Act that channel this discretion. For example, the Act requires the Secretary to

respond to petitions made by "[a]ny person" to modify the vaccine injury table, unless the petition is clearly frivolous. 42 U.S.C. § 300aa-14(c)(2) (1994). Importantly, the Act sets forth both procedural requirements that govern regulations to modify the injury table, *see* 42 U.S.C. § 300aa-14(c)(1) (requiring notice and comment rulemaking, a 180-day comment period, and opportunity for a public hearing), advisory bodies that the Secretary is required to consult, *see id.* § 300aa-14(d) (requiring the Secretary to solicit input from the Advisory Commission), and substantive requirements for the revised injury tables, *see id.* § 300aa-14(e) (requiring the Secretary to revise the vaccine injury table to include all recommended childhood vaccines).

Finally, the *Clinton* Court considered it important that the President was fulfilling Congress's policy under the Tariff Act when he suspended certain import duty exemptions, whereas he was clearly contravening Congress's policy judgment when he canceled spending items under the Line Item Veto Act. *See Clinton*, 524 U.S. at 444. The brief outline of the Vaccine Act already provided above demonstrates compellingly that the Secretary was executing congressional policy when she promulgated the 1995 Table. Indeed, the Act explicitly directed the Secretary to study pertussis vaccines and to promptly promulgate a revised injury table based on such findings. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-360, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-80. Thus, we conclude that the Secretary's actions in this case are controlled by *Field v. Clark*, rather than *Clinton*.

Under section 300aa-14(c) of the Vaccine Act, the Secretary does not have power to amend the original, legislatively-enacted Vaccine Injury Table. Instead, the Secretary merely has the power to promulgate revised injury tables that reflect current knowledge linking childhood vaccines to injuries. Congress intended that these improved tables provide the basis for compensation under the Act. We therefore conclude that section 300aa-14(c) of the Vaccine Act does not violate the Presentment Clause.

B

We next consider Terran's argument that, by granting the Secretary the power to promulgate revised vaccine injury tables, the Vaccine Act effects an unconstitutional delegation of legislative power to the Secretary. Under the "nondelegation doctrine," Congress may "seek [ ] assistance from another branch" of the Government, as long as "the extent and character of that assistance [are] fixed according to common sense and the inherent needs of Governmental co-ordination." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928). Accordingly, "[i]f Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power." *Id.* at 409.

We have little doubt that the Vaccine Act sets forth such an intelligible principle to guide the Secretary's actions. Again with reference to the statute, Congress has provided the Secretary with both substantive guideposts and procedural requirements that must be observed. For

example, the Initial Table in the Act itself operates as an intelligible principle that governs subsequent, administratively created tables. In the Initial Table, Congress identified the vaccines covered by the table, the illnesses or conditions for which compensation might be had, and the time period required for the first symptom or onset of each illness or condition. *See* 42 U.S.C. § 300aa-14(a) (1994). Although Congress gave the Secretary the power to revise the Initial Table by regulation, revised tables must adhere to this same format. *See id.* § 300aa-14(c)(3) (authorizing the Secretary to add or delete from the list of illnesses and conditions, and to change the time periods). And although the Secretary could in theory delete all entries in the table or, conversely, sweep in all possible illnesses or conditions, the Act constrains the Secretary's discretion. First, the Vaccine Act requires the Secretary to consult with the Advisory Commission on Childhood Vaccines before proposing rules to revise the injury table. *See id.* § 300aa-14(d). This Commission comprises health professionals, members of the public with family members who have suffered vaccine-related injuries or death, and legal representatives of vaccine victims and vaccine manufacturers, and is charged with the task of gathering information on vaccine-related injuries. *See id.* § 300aa-19. The Act also provides for automatic termination of the compensation program if the total number of awards exceeded a specified number within time frames established by Congress. *See id.* § 300aa-34. More generally, the Vaccine Act establishes a broad program to study and reduce the risk of childhood vaccines. *See, e.g.*, National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-360, §§ 312(a)-(d), 313(a), 1986 U.S.C.C.A.N. (100 Stat.) 3755,

3779-82 (directing the Secretary to request that the Institute of Medicine of the National Academy of Sciences conduct studies exploring the link between childhood vaccines with certain illnesses). Congress clearly intended the Secretary to be guided by the findings from such studies when she decides to promulgate regulations to revise the injury table. *See id.* § 312(c)-(d), 100 Stat. at 3780; 42 U.S.C. § 300aa-14(d) (1994).

Congress provided ample guidance and limits on the Secretary's authority to promulgate revised vaccine injury tables, and thus Congress's commitment of power to the Secretary under the Vaccine Act does not violate the nondelegation doctrine. Accordingly, the 1995 Table is a valid regulatory enactment.

IV

A

Having determined that the 1995 Table is valid, we finally turn to the merits of the case. Terran's first argument in favor of reversal, notwithstanding the validity of the regulations at issue, is that the 1995 Table should not apply to her, because her claim arose before the effective date of the regulations. That is, Terran argues that because Julie was assertedly injured by a vaccination on August 10, 1992, her claim arose well before the March 1995 effective date of the Table regulations. Terran suggests that to apply the 1995 Table to her case would work an impermissible retroactive application of law. We disagree.

While we concur with Terran's authoritative citation that "retroactivity is not favored in the law," *see Landgraf*

v. USI Film Prods., 511 U.S. 244, 264 (1994), it does not follow that the 1995 Table does not apply to her case. For it is equally clear that "where congressional intent is clear, it governs." *Id.* (quoting *Kaiser Aluminum & Chem. Corp. v. Bonjorno*, 499 U.S. 827, 837 (1990)). Here, the statute specifically states that newly-promulgated Table regulations "shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation." 42 U.S.C. § 300aa-14(c)(4) (1994). Terran's claim was filed in July 1995, four months after the effective date of the new regulations. *See* 42 C.F.R. § 100.3(c) (1996). This conclusively resolves the question; the 1995 Table applies to Terran's claims. *See Kaiser Aluminum*, 499 U.S. at 837-38.

B

Terran next argues that the Special Master erred in discounting the causation-in-fact testimony of her expert. The Special Master, applying the factors set forth in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), determined that the expert's theory regarding the causal link between the pertussis toxin and Julie's condition did not meet the standards for scientific reliability enunciated in *Daubert*.

Terran first argues that the application of *Daubert* to this realm of expert knowledge, "general medical issues," was erroneous. She suggests that the *Daubert* framework is narrowly intended to prevent the introduction of "junk science" into trials, rather than as a broader tool for analyzing the admissibility of scientific testimony. We disagree. To the extent we had any doubt at all regarding

the permissible use of the *Daubert* framework outside the "scientific" areas specifically discussed in that case, the Supreme Court's recent decision in *Kumho Tire Co. v. Carmichael*, 526 U.S. ___, 119 S.Ct. 1167 (1999), has clarified the issue. *Kumho Tire* specifically notes that the general principles of Daubert apply broadly to "scientific, technical, or other specialized knowledge," and that the rules of evidence require that the trial judge determine "whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline.' " *Id.* at 1175 (quoting *Daubert*, 509 U.S. at 592). Thus, the Special Master did not err in analyzing the proffered testimony according to *Daubert*.

Terran next argues that the Special Master improperly applied the *Daubert* factors to the expert's testimony. In particular, Terran suggests that the Special Master erred by requiring the evidence to meet each of the four *Daubert* factors.[2] However, we do not read the Special Master's decision as requiring that Terran's proffered evidence meet all of the *Daubert* factors. Instead, we view the Special Master's analysis as using *Daubert's* questions as a tool or framework for conducting the inquiry into the reliability of the evidence. *See Kumho Tire*, 119 S.Ct. at 1175 ("[Daubert's] list of factors was meant to be helpful,

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[2] The Daubert factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error, and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community. *See Daubert*, 509 U.S. at 592-95.

not definitive."). The Special Master found that the *Daubert* inquiry raised serious questions about the testimony, and thus concluded that the proffered theory of causation was not sufficiently reliable. *See Terran v. Secretary of Health & Human Servs.*, No. 95-45IV, slip op. at 14 (Fed. Cl. (Special Master) Jan. 23, 1998). Because we view the Special Master's application of the *Daubert* factors to be reasonable, *see Kumho Tire*, 119 S.Ct. at 1176 ("[A] trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony."), and do not discern any abuse of discretion in the analysis, *see Burns v. Secretary of Health & Human Servs.*, 3 F.3d 415, 417-18 (1993) (reviewing the Special Master's evidentiary determinations for abuse of discretion), we affirm the Special Master's decision to discount the testimony.

C

Terran's final argument is that the Special Master, and thus the Court of Federal Claims, did not address her "straightforward" causation-in-fact argument. That is, Terran suggests that while the Special Master rejected her proffered theory of the mechanism of Julie's injury, that court failed to consider whether an alternative and more straightforward clinical explanation of causation was nonetheless correct. As the Court of Federal Claims noted, however, Terran's "straightforward" argument rests entirely upon factual matters resolved against her, as well as upon those which have been held to be insufficient to establish a *prima facie* case. *See Terran v. Secretary of Health & Human Servs.*, No. 95-451V, slip. op at 9 (Fed. Cl. July 10, 1998). For example, Terran points to the

temporal association of the seizures with the DPT vaccination, which has been held to be insufficient proof of causation. *See Hasler v. United States*, 718 F.2d 202, 205 (Fed. Cir. 1983). Terran also posits that Julie exhibited a unique seizure disorder, even though this requires agreement with the expert testimony rejected as unreliable by the Special Master. In short, our review of the record has not uncovered any finding of fact or conclusion of law that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B) (1994). We thus are compelled to affirm the Special Master's rejection of Terran's causation-in-fact claim.

V

In summary, we hold that the Vaccine Act does not violate either the Presentment Clause of the Constitution or the nondelegation doctrine that emanates from separation of powers principles. We affirm the ruling by the United States Court of Federal Claims that the 1995 Table applies to these facts, and that Terran failed to present a prima facie case for compensation under the Act.

COSTS

No costs.

AFFIRMED

PLAGER, *Circuit Judge*, dissenting.

Under the United States Constitution, Congress may legislatively declare the rights and liabilities of its citizens in one, and only one, way, and that is by a "Bill which shall have passed the House of Representatives and the Senate, [and] shall, before it becomes a Law, be presented to the President of the United States" for approval or veto. U.S. Const. art. I, § 7, cl. 2 ("the Presentment Clause"); *see also Clinton v. New York*, 524 U.S. 417 (1998). Neither one House of Congress acting alone, *see INS v. Chadha*, 462 U.S. 919 (1983), nor the President or other Executive Branch official may constitutionally enact, amend, or repeal statutes. *See Clinton*, 524 U.S. at 438 ("There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes.").

In this case, Congress purported to provide for the amendment of existing legislation, which was otherwise valid and enforceable by the courts of the United States, in a manner different from that provided in the Constitution, namely by authorizing an Executive Branch official to do it. That effort must necessarily fail. The majority's valiant effort to uphold the purported amended legislation must also fail, since no amount of verbal adroitness can change the reality of what happened. I respectfully dissent.

1.

The essentials of this case are simple. In 1986 Congress enacted legislation, approved by the President,

which entitled persons injured by certain childhood vaccines to a financial recovery paid from the Treasury of the United States. The legislation, inter alia, set out in detail the particulars of certain injuries caused by the specified vaccines and the evidence of their happening; if a person established those particulars, he or she was entitled to a recovery. The injuries thus described were known as 'table injuries', since the particulars were set out in the legislation in the form of a Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14(a) (1994). Under the legislation as enacted, the detailed provisions contained in the table remain in effect indefinitely, that is, no 'sunset' or automatic termination provision was included in the legislation.

In a separate subsection of the legislation, § 300aa-14(c)(1)-(4), Congress purported to enable an Executive Branch officer, the Secretary of Health and Human Services, to amend the statute by changing the particulars contained in the table. The Secretary had authority "to modify" the table, § 300aa-14(c)(1); she could "add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided . . . . " § 300aa-14(c)(3). No restraints were placed upon the Secretary's exercise of the power – the power could be exercised at the discretion of the Secretary, when and as the Secretary chose – other than procedural steps which required, among other things, that the Secretary first confer with her Advisory Commission on Childhood Vaccines, and that the action be in the form of a rulemaking.

Some years later, in 1995, the Secretary chose to exercise that power, and purportedly amended the

statute. Plaintiff-Appellant in this case alleges that she would be entitled to an award under the terms of the Congressionally-enacted table, but that under the table as amended by the Secretary she is not so entitled. She challenges the application of the amended statute to her case.

Given the clarity with which the Constitution speaks to this question, and the Supreme Court's unequivocal honoring of the Presentment Clause in *Chadha* and *Clinton*, one might suppose that this would be a not-difficult case to decide. The majority, however, seeks to find a way around the Constitution, and it is to that effort that I now turn.

2.

As a preliminary matter, I agree with the result reached by the majority in Part IIA of its opinion, i.e., that the Court of Federal Claims has jurisdiction to adjudicate Terran's constitutional challenges to the Vaccine Act, though I cannot join the majority's convoluted analysis in reaching that conclusion. The majority devotes considerable energy to analyzing whether Terran's claim is for money damages. The "money damages" requirement for claims before the Court of Federal Claims arises from that court's jurisdiction under the Tucker Act. *See, e.g., United States v. Mitchell*, 463 U.S. 206, 216-17 (1983); *United States v. Testan*, 424 U.S. 392, 398 (1976). While it is true that the Court of Federal Claims is a court of limited jurisdiction, the Tucker Act is not the only statute expressly granting that court jurisdiction.

As the majority seems to recognize, slip op. at 11, the Vaccine Act itself provides the Court of Federal Claims with jurisdiction to determine whether Terran is entitled to compensation and the amount of such compensation. *See* 42 U.S.C. § 300aa-12(a) (1994); *Beck v. Secretary of the Dep't of Health and Human Servs.*, 924 F.2d 1029, 1036 (Fed. Cir. 1991). This grant of jurisdiction is independent of any jurisdictional grant under the Tucker Act. It is therefore unnecessary to consider, as the Court of Federal Claims did, whether Terran's constitutional challenge to the Vaccine Act is based on a "money-mandating provision" of the Constitution. The only question we need address is whether in exercising its jurisdiction under the Vaccine Act, the Court of Federal Claims may properly consider the constitutional issues presented.

The Court of Federal Claims has jurisdiction "to determine if a petitioner . . . is entitled to compensation under the [National Vaccine Injury Compensation] Program." 42 U.S.C. § 300aa-12(a). Terran raises her constitutional challenge as part of a claim for compensation over which the Court of Federal Claims clearly has jurisdiction. Resolution of that constitutional challenge directly impacts the determination of whether Terran is entitled to compensation. As the majority correctly concludes, the Vaccine Act gives the Court of Federal Claims the power that is necessary to decide the issue of Terran's compensation, including the power to address the constitutional challenge to the Vaccine Act. *See Beck*, 924 F.2d at 1036; *see also Rodriguez v. Secretary of the Dept. of Health and Human Servs.*, 34 Fed. Cl. 57 (1995) (addressing petitioner's claim that special master's interpretation of § 11(c)(1)(D)(i) of the Vaccine Act violates the Equal Protection clause of the

Constitution), *aff'd sub nom. Black v. Secretary of the Dep't of Health and Human Servs.*, 93 F.3d 781 (Fed. Cir. 1996).

Moving on to Part IIB of its opinion, the majority there considers at some length whether 42 U.S.C. § 300aa-32 precludes the Court of Federal Claims from reviewing Terran's constitutional claims; the majority concludes it does not. Again, I agree with the majority's conclusion, but I get there simply because § 300aa-32 is irrelevant to the constitutional challenges at issue here.

By its plain language, § 300aa-32 provides for the review of a *regulation* promulgated under the Vaccine Act. The purpose of the 60-day review period limitation is to preclude a later-filed challenge to the correctness of the administrative action, for example, a challenge that the Secretary did not follow proper rulemaking procedures in creating the revised table, or exceeded the scope of authority the statute granted. That type of challenge was often raised in enforcement actions in other areas, environmental law being an example, until Congress inserted counterparts of § 300aa-32 into the appropriate statutes.

Terran's claim in this case is not a challenge to the manner of promulgation or to the content itself of the regulation that amended the 1995 Table. It is instead a challenge to the underlying enabling statute, 42 U.S.C. § 300aa-14(c), that purports to give the Secretary the power to promulgate the regulation at all. Section 300aa-32 does not govern review of the statute. Thus, I find the majority's discussion of whether § 300aa-32 is intended to be always permissive (which I think is simply

wrong), and the circumstances, if any, under which judicial review of a regulation beyond the 60-day period is proper, to be unnecessary to the decision in the case.

3.

The heart of my dissent lies in my disagreement with the majority's conclusion in Part IIIA that 42 U.S.C. § 300aa-14(c) does not violate the Presentment Clause of the Constitution. (The majority opinion initially states the question to be one of "separation of powers principles," slip op. at 2, but, as the Supreme Court observed in *Clinton*, 524 U.S. at 448, the question of compliance with Art. I, § 7 is a distinctly different question from the question of whether a statute "impermissibly disrupts the balance of powers among the three branches of government.")

Congress enacted into law the initial version of the Vaccine Injury Table by following proper enactment and presentment procedures in accordance with Article I of the Constitution. As noted, the Supreme Court as recently as last year has made clear that the Presentment Clause requires that any modification to a statute must follow those same procedures. *See Clinton*, 524 U.S. at 448-49. Because 42 U.S.C. § 300aa-14(c) gives the Secretary unilateral power to *amend* the Vaccine Injury Table without complying with the bicameralism and presentment procedures required for legislative acts, the statute violates the Presentment Clause.

The majority holds that the Vaccine Act does not authorize the Secretary to *amend* the original Vaccine Injury Table, but that it merely authorizes the creation of

an entirely new table by regulation, the new table of course superseding the old one. That is little more than a transparent attempt to find a verbal formula for disguising the reality of what transpired. The Vaccine Act explicitly provides that the "Secretary may promulgate regulations to *modify* . . . the Vaccine Injury Table." 42 U.S.C. § 300aa-14(c) (1994) (emphasis added). Despite this admission by Congress that it intended to give the Secretary the power to amend the Vaccine Injury Table, the majority concludes that no amendment occurred because the initial Vaccine Injury Table remains codified in its original form.

Indeed, the crux of the majority's argument derives from the following syllogism: "This new table applies only prospectively. . . . The Initial Table remains codified and unaltered, and continues to apply to all petitions filed before the revision. Therefore, the Initial Table is not amended." Slip op. at 17. The unstated major premise is that an amendment that leaves the earlier provision unrepealed means that the earlier provision is not "amended." It does not require much analysis to recognize the fundamental flaw in that argument.

When Congress changes an existing law, for example by increasing the amount of a penalty for prohibited conduct, or by modifying the criteria for an entitlement, it is almost invariably the case that the provisions of the original statute remain in effect for all cases arising prior to the effective date of the amendment, and that the changed requirements apply only prospectively, to newly-arising matters. As the Supreme Court has admonished, "retroactivity [of legislation] is not favored in the law." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 264 (1994),

with the result that Congress rarely makes such changes retroactive. Under the majority's syllogistic reasoning, it would follow that Congress does not "amend" a statute when it makes changes in existing legislation, and leaves the earlier enactment unrepealed; only in the rare case of total repeal with retroactivity is the change an "amendment." That conclusion takes generally understood legal terminology and stands it on its head.

Putting aside such verbal obfuscation, what is clear is that, as a result of the regulation promulgated by the Secretary in 1995, the initial Vaccine Injury Table is no longer legally effective with regard to cases arising after the effective date of the amendment. The Secretary has deleted a provision which, but for the deletion, would be available for the benefit of persons like Terran. Absent the regulation, the original Vaccine Injury Table would continue to apply to Terran and all others similarly situated; with the regulatorily-amended Table, only the amended table applies to those who file their petitions after the effective date of the regulation.

It matters not whether we say, as the majority says, that the original Vaccine Injury Table was not amended, but that just a new Table was put into law, or whether we acknowledge the obvious reality that the then-existing Table was effectively amended by the regulation. The result is the same – the statutory table as enacted by Congress does not apply to petitions filed after the Secretary's regulation took effect. To paraphrase the words the Supreme Court used in *Clinton*, "[i]n both legal and practical effect, the [Secretary] has amended [an Act] of Congress by repealing a portion of [it]," and "[t]he

cancellation of one section of a statute may be the functional equivalent of a partial repeal even if a portion of the section is not canceled." *Clinton*, 524 U.S. at 438, 441.

In further support of its judgment, the majority suggests that the statute by inference has a 'sunset' provision. That simply is not the case. Congress did not decide when the initial Vaccine Injury Table would become ineffective, either by specifying a date or by defining a particular event that would render the initial table ineffective. To suggest, as the majority does, that the Secretary's action is an event selected by Congress to trigger the effective repeal of the initial Vaccine Injury Table is nothing more than circular reasoning, for it is the Secretary's action in amending the table that itself "repeals" the initial Vaccine Injury Table.

Congress could have chosen to write the statute differently. If Congress in the Vaccine Act had specified certain external events upon the happening of which the enacted table became no longer effective, and at which time the Secretary was to create a revised injury table, and left to the Secretary the determination of when the specified events in fact occurred, the analysis *might* be different. *See Clinton*, 524 U.S. at 445 (explaining that the Tariff Act of 1890 was upheld in *Field v. Clark*, 143 U.S. 649 (1892), because "Congress itself made the decision to suspend or repeal the particular provisions at issue upon the occurrence of particular events subsequent to enactment, and it left only the determination of whether such events occurred up to the President"). But we are not presented with such a situation. The Vaccine Act gives the Secretary complete authority to modify the table, unrestrained by any prerequisite conditions established

by Congress, beyond those procedural steps alluded to earlier.

As an alternative, in enacting the Vaccine Act Congress, presumably without violating the Constitution, might have established appropriate criteria under which the Secretary was given authority to create the initial table through an administrative rulemaking procedure, along with the power to revise the table from time to time consistent with those criteria. Congress, however, did not choose this route either, and instead, for whatever reason, included the initial Vaccine Injury Table in the statute itself. Having done so, Congress can render the enacted statute inapplicable to those who come within it only by repealing or amending the statute in compliance with the bicameralism and presentment procedures of Article I of the Constitution.

The majority's statement, slip op. at 17, that Congress intended that the Secretarially-revised table would supersede its statutory table is irrelevant. *See Clinton*, 524 U.S. at 445-46 ("The fact that Congress intended such a result is of no moment."). Thus there is little question that § 300aa-14(c), as Congress wrote it and which purports to empower the Secretary to modify the statutorily-created Vaccine Injury Table, violates the Presentment Clause of the Constitution.[1]

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[1] Because I conclude that 42 U.S.C. § 300aa-14(c) clearly violates the Presentment Clause, I find it unnecessary to address the more difficult question of whether the statute as written complies with the minimum requirements for a valid delegation of legislative power, the issue considered by the majority in Part IIIB. Therefore, I do not join that part of the majority's opinion.

4.

Words have consequences. The Constitution's constraints have served us well. Judges regularly attend to the constraints the Constitution places upon their own performance, such as the requirement for a genuine "case" or "controversy" before a federal court may exercise judicial power. *See* U.S. Const. art. III, § 2. When a case is before us, it is our obligation under the law to ensure that the other Branches equally conform to the Constitution's mandates, even when doing otherwise would seem to be simpler or more convenient.

Because I would hold that the 1995 attempt by the Secretary to revise the initial Vaccine Injury Table is of no legal effect, I would not reach Plaintiff's alternative theory of causation-in-fact which the majority addresses in Part IV of its opinion. Instead, I would vacate the judgment of the Court of Federal Claims, and remand the case to that court with instructions to analyze Terran's claims under the legislatively-enacted table in 42 U.S.C. § 300aa-14(a), and to process her claims accordingly. I respectfully dissent from the contrary conclusion reached by the majority.

In the United States Court of Federal Claims

No. 95-451 V

(FILED: July 10, 1998)

****

MICHELE Y. TERRAN, as Legal Representative of JULIE F. TERRAN, a minor,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Respondent.

National Childhood Vaccine Injury Act; Standard of Review; Retroactivty of Injury Table.

****

Andrew W. Dodd, Torrance, California, for petitioner.

Claudia Gangi, United States Department of Justice, Washington, D.C., for respondent, with whom were *Assistant Attorney General Frank W. Hunger, Director Helen M. Goldberg, Deputy Director John Lodge Euler,* and *Assistant Director Gerard W. Fischer,* for respondent.

ORDER

TIDWELL, *Senior Judge*:

This case is before the court on petitioner's motion for review of the January 23, 1998 decision of Special Master Abell denying compensation under the National Child Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa-1 – 34 (1994). *See Terran v. Secretary of HHS,* No.

95-451V, 1998 WL 55290 (Fed. Cl. Sp. Mstr. Jan. 23, 1998) (dismissal order). For the reasons set forth below, the court denies petitioner's motion for review and affirms the Special Master's decision.[1]

FACTS

On behalf of Julie F. Terran ("Julie"), petitioner filed a petition on July 12, 1995 for compensation under the National Childhood Vaccine Injury Act. Julie was born on February 10, 1992, in Phoenix, Arizona. She was in good health and her APGAR[2] scores were eight/nine when discharged from the hospital on February 11, 1992. On March 27, 1992, when Julie was two months old, she received her first DPT vaccination. She received her second DPT vaccination on June 3, 1992, when she was three and one-half months old; her third DPT vaccination on August 10, 1992, when she was 6 months old; and her fourth DPT vaccination, which was an acellular DPT vaccination, on September 22, 1993. Only the third DPT vaccination is at issue in this case.

On August 11, 1992, the day after her third DPT vaccination, Julie suffered a seizure episode lasting approximately seven seconds and causing one of her

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[1] Consequently, petitioner's May 6, 1998 request for oral argument is denied.

[2] Numerical value assigned to the evaluation of the physical status of a newborn infant based on heartbeat rate, respiratory (breathing) effort, muscle tone (firmness of muscles), response to stimulation, and skin color. The best score is ten. *See* J.E. Schmidt, M.D., *Attorney's Dictionary of Medicine and Word Finder* at A-327 (1995).

arms to become stiff. The following day, Julie experienced four afebrile seizures, each roughly one minute in length. Immediately after the four seizures, Julie was rushed via ambulance to Phoenix's Children's Hospital at Good Samaritan Medical Center. On the way to the hospital, Julie played with her oxygen mask and was observed to be active, alert, and non-toxic. Julie was admitted and remained hospitalized for observation from August 12-14, 1992.

On August 13, 1992, Julie suffered another seizure lasting approximately five and one-half minutes. The hospital staff prescribed the anti-convulsant Phenobarbital to Julie. In total, Julie experienced approximately twelve minutes of seizure activity in the seven days following her third DPT vaccination. The seizures continued throughout the next year. On September 12, 1992, Julie suffered a seizure lasting approximately fifty minutes, despite being on Phenobarbital at the time.

Before the third DPT vaccination, Julie's doctor performed several tests to determine if she had permanent brain damage resulting from a meningocele lump removed from her skull before the third DPT vaccination. Tests completed prior to her third DPT vaccination indicated she had no brain abnormalities. On May 18, 1992, an MRI scan reported her brain structure as normal. A biopsy indicated the lump was not cancerous. On May 27, 1992, the lump was surgically removed. Dr. Manwaring, a board certified pediatric neurosurgeon, completed the lump removal follow up and determined Julie's pre-immunization neurological condition to be unremarkable except for moderate strabismus. After the third DPT vaccination, Julie had MRI's on May 21, 1993 and August 13,

1993, which showed no structural pathology in her brain. On September 13, 1993, Dr. Berebitsky, the pediatrician who administered standard well-baby care to Julie, noted that Julie was "well appearing" and "neurologically intact."

Dr. Berebitsky first noted a problem with Julie's neurological condition in November, 1993. At this time, she had a borderline passing score on the Denver Developmental Screening Test. Although genetic test results in June, 1995 and July, 1996 were normal, Julie's seizures continue today and she is currently mentally retarded.

DISCUSSION

I. Standard of Review

In reviewing the Special Master's decision, the court may (1) uphold the findings of fact and conclusions of law and sustain the decision, (2) set aside any findings of fact or conclusions of law found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and issue its own findings of fact and conclusions of law," or (3) remand the petition to the Special Master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e)(2); *see McCarren v. Secretary of HHS*, 40 Fed. Cl. 142, 145-47 (1997) (clarifying that the standard of review is not de novo, but is the narrow "arbitrary and capricious" standard for both fact and law). The scope of review for this standard is exceedingly narrow; a court "may not substitute its own judgment for that of the Special Master if the Special Master has considered all relevant factors, and has made no clear error of judgment." *Costa v. Secretary of HHS*, 26 Cl. Ct.

866, 868 (1992) (quoting *Loe v. Secretary of HHS*, 22 Cl. Ct. 430, 432 (1991)).

II. Recovery under the Vaccine Act

Under the Vaccine Act, certain prerequisites must be met before petitioner can receive compensation. These prerequisites include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine, 42 U.S.C. § 11(c)(1)(D)(i); (2) that petitioner incurred in excess of $1000 in unreimbursable vaccine related expenses, 42 U.S.C. § 11(c)(1)(D)(i); (3) that the vaccine was administered in the United States, 42 U.S.C. § 11(c)(1)(B)(i)(I); (4) that petitioner did not previously collect a judgment or settlement in a prior civil action, 42 U.S.C. § 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative, 42 U.S.C. § 11(b)(1)(A). These requirements are not at issue in this case.

Recovery under the Act also requires plaintiff to establish causation through one of two methods. First, causation may be presumed if the claimant establishes, through medical records or expert testimony, a claim or an injury listed in the Vaccine Injury Table ("Table"), 42 U.S.C. § 300aa-14(a), and shows by a preponderance of the evidence that the injury occurred within the time period prescribed by the Table. *See id.* § 300aa-13(a)(1)(A). The Table "determines by law that the temporal association of certain injuries with the vaccination suffices to show causation . . . [replacing] traditional tort standards of causation in fact with a causation in law based on

temporal association." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

Alternatively, claimants can recover under the Vaccine Act by showing causation in fact if the injury is either not included in the Table, or if a listed table injury has occurred after the corresponding time period has run. *See* 42 U.S.C. § 300aa-11(c)(1)(C). Compensation for non-Table injuries is authorized under 42 U.S.C. § 300aa-11(c)(1), and includes any illness, disability, injury, or condition not listed on the Table or not meeting the Table's requirements. Causation in fact is more difficult to establish because it requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. *See Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Strother v. Secretary of HHS*, 18 Cl. Ct. 816, 820 (1989). In addition, the logical sequence of cause and effect must be supported by medical or scientific evidence. *See* 42 U.S.C. § 300aa-13(a)(1); *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983). Though it is not necessary to show that the vaccination caused the injury with scientific certainty, *see Bunting v. Secretary of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991), a mere temporal association between the injury and the vaccination is not sufficient to establish causation. *See Hasler* 718 F.2d at 205. If a claimant substantiates a claim by either method, the burden of proof shifts to the government to prove that the illness, injury, or death is due to factors unrelated to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B).

III. Revision of the Injury Table

The Secretary of Health and Human Services is authorized to revise the Table by adding or deleting injuries from the table or by altering the required time periods for onset of injury. *See* 42 U.S.C. § 300aa-14(c)(1). When promulgating new regulations, the Secretary "shall provide for notice and opportunity for a public hearing and at least 180 days of public comment." *Id.* Modifications to the table "shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulations." *Id.* § 300aa-14(c)(4).

On February 8, 1995, the Secretary of the Department of Health and Human Services released regulations removing residual seizure disorder ("RSD") from the Table and altering the definition of encephalopathy. These regulations went into effect on March 10, 1995, and petitioner filed her claim four months later on July 12, 1995. Petitioner alleges that Julie suffers from RSD and encephalopathy as previously defined, and thus would be entitled to compensation if the Table had not been amended. On review, petitioner raises two arguments involving application of the modified Table to the case.

A. Constitutional Argument

First, petitioner contends that allowing the Secretary to modify the Table is unconstitutional because it is a legislative act not subject to bicameral approval by the House and Senate, and presentment to the President. *See* Pl.'s Mot. for Review at 11-13 (Feb. 12, 1998). The Court

of Federal Claims does not have jurisdiction to hear claims that do not obligate the Federal Government to pay money damages. *See Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (no jurisdiction over claims based on due process and equal protection under the Fifth Amendment); *Greider v. Secretary of HHS*, 23 Cl. Ct. 348, 350 (1991); *Adams v. United States*, 20 Cl. Ct. 132, 135 (1990); *Lark v. United States*, 17 Cl. Ct. 567, 569 (1989). Petitioner's constitutional claim is not based on a money mandating provision of the constitution, and as a result, the Court of Federal Claims does not have jurisdiction to decide the constitutional issue.

B. Validity of Table Regulations

Under the Act, challenges to the substance and validity of regulations not involving constitutional issues must be made in a court of appeals of the United States within sixty days of promulgation of the regulation if grounds for the challenge arise before promulgation of the regulation. *See* 42 U.S.C. § 300aa-32. In *O'Connell v. Secretary of Health and Human Services*, 79 F.3d 170 (1st Cir. 1996), plaintiff challenged the propriety of the procedures surrounding the implementation of the March 10, 1995 Table modifications and related definitions, but the plaintiff did not raise constitutional issues. The court held that the Secretary had the authority to issue the regulations and exercised that authority in a procedurally appropriate and substantially permissible manner. *See id.* at 182. Although the Vaccine Act only expressly permits the Secretary to make additions and deletions to the Table, the court held that the Act implicitly grants the Secretary

the authority to revise the Qualifications and Aids to Interpretation accompanying the Vaccine Act. *See id.* at 175-76. Therefore, it was permissible for the Secretary to remove RSD from the Table and change the definition of encephalopathy. Petitioner, who first experienced seizures in 1992 and demonstrated a noticeable neurological condition in November, 1993, had the opportunity, not only to comment on the proposed regulations, but also could have challenged the regulations in a United States court of appeals within sixty days of the promulgation of the regulation. The Vaccine Act specifically limits when such challenges can be made and in what court the challenges can be brought. Failure to comply with the statute prevents petitioner from objecting to the substance of the modifications or the way in which they were enacted.

C. Retroactive Application of Table Modifications

Petitioner argues that the modifications to the Injury Table should not apply retroactively because her claim arose before the effective date of the regulations. Petitioner relies on *Landgraf v. USI Film Products*, 511 U.S. 244 (1994), to establish a non-retroactive presumption for federal legislation. Although there is a deeply rooted presumption against retroactive legislation, "[w]here congressional intent is clear, it governs." *Id.* at 264-65. The Vaccine Act expressly states that revisions to the Table will apply to petitions "filed after the effective date of such regulation." 42 U.S.C. § 14(c)(4). In addition to the statute's express language, the regulations encourage the Special Masters "to apply scientific findings which form the basis of the revised table where appropriate."

National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7679. Retroactive provisions often serve legitimate purposes, such as to correct mistakes or to give comprehensive effect to new laws. *See Landgraf*, 511 U.S. at 267-68. The drafters of the Vaccine Act recognized research concerning vaccine related injuries was not complete, and "research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available the Secretary or the Advisory Commission of Childhood Vaccines may propose to revise the table." H.R. Rep. No. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Retroactive application of Table revisions allows cases to be decided using the most accurate causation information, regardless of when the injury occurred.

In addition, the rationale behind the presumption against retroactivity is not applicable in this case. In *Landgraf*, the court states that absent clear congressional intent for retroactivity, there is a presumption against retroactivity because persons "should have an opportunity to know what the law is and to conform their conduct accordingly." *Landgraf*, 511 U.S. at 265. With the Vaccine Act, however, it is impossible for a child to conform his or her injury to the old Table, so the reasoning behind the non-retroactivity presumption is not applicable in this case.

Petitioner also argues that there should be a presumption against retroactive application of the Table because Julie had a "vested right in a cause of action for asserted vaccine-related injury on or about August 10,

1992." *See* Pl.'s Mot. for Review at 11. First, "the Vaccine Act does not implicate any 'fundamental right' . . . [because] a 'noncontractual claim to receive money from the public treasury enjoys no constitutionally protected status.' " *Black v. Secretary of HHS*, 93 F.3d 781, 787 (Fed. Cir. 1996) (citing *Weinberger v. Salfi*, 422 U.S. 749, 772 (1975)). The mere fact that the "statute is retroactive does not make it unconstitutional [because] a legal claim affords no definite enforceable property right until reduced to a final judgment." *Arbour v. Jenkins*, 903 F.2d 416, 420 (6th Cir. 1990) (citing *Sowell v. American Cyanamid Co.*, 888 F.2d 802, 805 (9th Cir. 1989)) (application to Federal Employees Liability Reform and Tort Compensation Act). Julie does not have an automatic right to compensation until the Special Master or an appellate court rules that she does. Therefore, her rights cannot be abridged until there is a final judgment. Second, the Table is revised to reflect advances in modern medical science. Application of the new Table to petitioner's case is neither unfair nor does it deprive her of any rights because current medical research does not establish a presumption of causation between the pertussis vaccine and RSD or encephalopathy as defined by the old Table. Although Julie may have been able to prove causation under the old Table using prior medical evidence, modern medical research prevents Julie from proceeding under a Table causation theory.

IV. Causation in Fact

Petitioner concedes that there is no Table Injury under the present Table, and in the alternative, argues

that the Special Master's conclusion concerning causation in fact is erroneous because the Special Master inappropriately discounted petitioner's expert Dr. Menkes and never ruled on petitioner's straightforward clinical explanation of causation. The arbitrary and capricious standard applied in the review of Vaccine Act cases is highly deferential. *See Hines*, 940 F.2d at 1528. The court cannot merely substitute its judgment for the judgement of the decision maker. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Reversible error is extremely difficult to demonstrate "[i]f the Special Master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision. . . . " *Hines*, 940 F.2d at 1528. The central consideration is whether the Special Master acted rationally. *See id.* (citing *Midtec Paper Corp. v. United States*, 857 F.2d 1487 (D.C. Cir. 1988)); *United States v. Garner*, 767 F.2d 104, 116 (5th Cir. 1985); *Summar v. Secretary of HHS*, 24 Cl. Ct. 440, 443 (1991).

Petitioner seeks to prove causation in fact with the testimony of Dr. Menkes, who is board certified in pediatrics and neurology and is a consultant for the Committee on Adverse Vaccine Reactions for the Institute of Medicine. Dr. Menkes theorized that the pertussis toxin can cause a seizure disorder with potential evolution to retardation by entering the brains of young children (under six months) when the blood brain barrier is not yet operative. The pertussis toxin can also enter the brain of a young child with a developed blood-brain barrier because the anti-toxins in the vaccine lower the blood-brain barrier through a process called pinocytosis and allow the pertussis toxin to enter the brain. In addition,

Dr. Menkes opined that Julie suffered a complicated seizure within the parameters of National Childhood Encephalopathy Study (NCES), which establishes an association between the pertussis vaccine and encephalopathy.

The Special Master analyzed whether petitioner advanced a reputable and reliable medical or scientific explanation supporting the theory that the pertussis vaccine caused Julie's injuries. The Special Master applied *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to analyze whether there was an objective, independent validation of the expert's theory, and thus whether the theory was reliable. In *Daubert*, the court generated four factors to determine whether scientific evidence was relevant and reliable, and therefore, admissible under the Federal Rules of Evidence. These factors are (1) general acceptance in the scientific community, (2) whether the theory has been subjected to peer review and publication, (3) whether it can and has been tested, and (4) whether the known potential rate of error is acceptable. *See Daubert*, 509 U.S. at 593-94. The Special Master recognized the relevance of the *Daubert* analysis, but also states that the reliability determination is not limited to the *Daubert* factors. The Special Master concluded the causation theory presented by petitioner's expert did not meet the standards of scientific reliability enunciated in *Daubert*.

In *Estep v. Secretary of HHS*, 28 Fed. Cl. 664 (1993), the court objected to the use of *Daubert* in a vaccine case because the Supreme Court applied the *Daubert* analysis to determine admissibility of evidence under the Federal Rules of Evidence, which do not apply in Vaccine cases.

See id. at 668 n.1. Although the Federal Rules of Evidence do not apply in vaccine cases, the court believes *Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence. *See Leary v. Secretary of HHS*, No. 90-1456 V, 1994 WL 43395, at *9 (Fed. Cl. Sp. Mstr. Jan. 31, 1994). While the Supreme Court designed the test to determine whether evidence is relevant and reliable in the context of the Federal Rules of Evidence, it is equally capable of being used to determine whether information is relevant and reliable in the context of the Vaccine Act. It was not arbitrary and capricious for the Special Master to apply *Daubert* in this case to determine that Dr. Menkes' theory was not reliable scientific evidence. His theory has never been published, it has not been tested on humans, the rate of error is completely unknown, and Dr. Menkes admits that only 20% of professionals in his field would support his theory.

Petitioner objects to the Special Master's application of the *Daubert* guidelines, arguing that *Daubert* requires a flexible analysis designed to eliminate "junk science." Petitioner contends that correct application of the guidelines establishes that Dr. Menkes' theory is not "junk science" and should be admissible. In support of this argument, petitioner asserts that the theory has been sufficiently tested on animals, the animal testing results have been published, the rate of error prong does not apply because there is no scientific technique at issue, 80% of pediatric neurologists view the theory as valid, and 20% agree with the theory. The Special Master held that Dr. Menkes' theory did not by a preponderance of the evidence meet the standards of scientific reliability

enunciated in *Daubert*. The Special Master did not conclude that the Dr. Menkes' theory was junk science nor that the theory was inadmissible. The Special Master applied *Daubert* to measure the reliability and credibility of Dr. Menkes' theory compared to the theories offered by the respondent. It was not irrational for the Special Master to conclude that the theory was unreliable. The theory has never been tested on humans. Dr. Menkes admitted that he did not write a paper on the theory because "he know[s] it would never have been published." Dr. Menkes also noted that the theory is "not in the main stream of thought," and he admitted that while 80% of pediatric neurologists may view the theory as valid, only 20% would concur with his findings of causation. Therefore, it was not arbitrary and capricious for the Special Master to conclude that the theory was not sufficiently reliable to prove by a preponderance of the evidence that the DPT vaccine caused Julie's injuries.

The Special Master had the opportunity to observe the testimony, consider the comportment of the witnesses, and ask questions of each witness. The Special Master was uniquely able to make witness credibility determinations. The Special Master is not bound by the opinions of the expert witnesses and can reject the testimony for reasonable basis. 42 U.S.C. § 300aa-13(b)(1); *Aea v. United States*, 26 Cl. Ct. 878, 881 (1992), *aff'd* 6 F.3d 787 (Fed. Cir. 1993). Based on the *Daubert* analysis and the Special Master's observance and questioning of the witness, the Special Master's conclusion that the expert evidence was not sufficiently reliable was not irrational nor arbitrary and capricious.

The Special Master found the conclusions of the Institute of Medicine ("IOM") of the National Academy of Sciences to be credible.[3] The Vaccine Act charges the IOM to review the medical and scientific literature on possible adverse consequences of pertussis and rubella vaccines and to prepare a report on the results of its review. The Special Master concluded that the charge given to the IOM and the scope of its review made its conclusions authoritative. *See Terran*, 1998 WL 55290, at *10. Under the IOM report, there is a causal relationship between the DPT vaccination and febrile seizures. Since Julie experienced afebrile seizures, the IOM report does not establish causation by a preponderance of the evidence. Second, the IOM report concludes that there is a causal relationship between the DPT vaccination and chronic nervous functions that meet NCES criteria. To comply with the NCES study, the child must either suffer an acute encephalopathy, thirty minutes of seizure activity within seven days of the vaccination, or a complicated seizure which is characterized by a coma lasting two hours or more, seizures followed by paralysis, or other neurological signs not previously present lasting 24 hours or more. Julie did not experience an altered level of consciousness, as required for an acute encephalopathy. She only experienced twelve minutes of seizure activity within seven days of the vaccination. Finally, Julie did not experience a complicated seizure because she did not lapse into a

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[3] The IOM's conclusions were published in two reports: Institute of Medicine, *Adverse Affects of Pertussis and Rubella Vaccines* (Nat'l Academy Press 1991) and Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (Nat'l Academy Press 1994).

coma, experience paralysis, or demonstrate other neurological signs. The Special Master carefully considered the merits of the IOM study and rationally decided it was reliable. He also considered Julie's medical history, compared it to the IOM requirements, and concluded that her injuries did not comply with the IOM study and thus, petitioner failed to establish causation under the IOM report.

Petitioner also argues that the Special Master failed to rule on her straightforward clinical explanation of causation and that petitioner established a prima facie case. First, petitioner argues that Julie suffered an encephalopathy in close proximity to the DPT vaccination. Although the Special Master concluded that Julie suffers from encephalopathy now, it is not proven that she had encephalopathy immediately after the DPT vaccination because she was alert, responsive and non-toxic in the ambulance. In addition, temporal association is not sufficient proof of causation. *See Hasler*, 718 F.2d at 205. Second, petitioner argues that there is no other viable explanation for Julie's disorder. The Federal Circuit has held that "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual and legal causation." *See Grant*, 956 F.2d at 1149. Third, petitioner states that Julie was normal prior to the vaccination, but this cannot prove causation alone because children can develop seizure disorders or encephalopathy for numerous reasons unrelated to the DPT vaccination. Finally, petitioner argues simply that Julie exhibited a unique seizure disorder triggered by the pertussis vaccine and that her medical history matches Dr. Menkes' theory. Simply stating that causation is

proven without supporting evidence, or using evidence that has already been discredited by the Special Master is not sufficient to establish a claim by a preponderance of the evidence.

CONCLUSION

Upon review of Special Master Abell's decision and applicable case law, the court finds that the petitioner has failed to demonstrate that denial of their claim was arbitrary, capricious, or otherwise not in accordance with the law. As a result, petitioner's motion for review is denied. The court pursuant to 42 U.S.C. § 300aa-12(e)(2)(A), hereby sustains the Special Master's January 23, 1998 decision. The Clerk of the court is directed to enter judgment accordingly.

IT IS SO ORDERED.

/s/ M. R. Tidwell
MOODY R. TIDWELL
Senior Judge

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 95-451V

(Filed: January 23, 1998)

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claims that the pertussis toxin component of the diphtheria-pertussis-tetanus (DPT) vaccine, administered on 10 August 1992, caused Julie's residual seizure disorder (RSD) and encephalopathy.

On 10 October 1995, respondent filed a report concluding that petitioner is not entitled to compensation under the Act. On 5-6 March 1997, the court conducted an evidentiary hearing in Los Angeles, California. Petitioner presented the testimony of Dr. Gary Berebitsky, treating physician of Julie, and Dr. John Menkes, pediatric neurologist. Dr. Robert Baumann, pediatric neurologist, testified on behalf of respondent.

Following a review of the entire record, and for the reasons stated *infra*, the undersigned finds that petitioner is not entitled to compensation under the Act.

I. FACTS[2]

Julie was born on 10 February 1992 in Phoenix, Arizona. Pet.Aff., at 2. Her APGAR scores were eight/nine and she was discharged in good health from the hospital on 11 February 1992. Pet.Ex. 1, at 19. She received her first DPT vaccination on 27 March 1992 at two months of age. Tr. at 22. She received her second DPT vaccination on 3 June 1992 at three and one-half months of age. Tr. at 22. She received her third DPT vaccination on 10 August 1992 at six months of age. Tr. at 22. Her fourth DPT vaccination, administered on 22 September 1993, unlike the three previous DPT vaccinations, was an acellular

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[2] Reference to the transcript of the 5-6 March 1997 evidentiary hearing will be made as "Tr. at ___."

DPT vaccine. All of these vaccines were given by Dr. Gary Berebitsky, Julie's pediatrician, at her well-baby care checkups. Tr. at 22. The third DPT vaccination is the one that is at issue in this case.

The day after her third DPT vaccination, on 11 August 1992, Julie suffered a seizure episode lasting approximately seven seconds in which one of her arms became stiff. Pet.Aff., at 2. On 12 August 1992, Julie experienced four afebrile seizures, each about one minute in length. Tr. at 109; Pet.Ex. 4, at 333. Following her 12 August 1992 seizures, Julie was rushed to Phoenix Children's Hospital (PCH) at Good Samaritan Medical Center via ambulance. Pet.Aff., at 3. She played with her oxygen mask during the trip, and was noted as alert, active, and non-toxic. Pet.Ex. 4, at 203-4; Pet.Ex. 10, at 436. Julie was admitted to PCH for observation and remained hospitalized from 12-14 August 1992. In the presence of hospital personnel, on 13 August 1992, Julie suffered another seizure lasting approximately five and one-half minutes. Pet.Aff., at 3; Pet.Ex. 4, at 235. The hospital personnel administered the anti-convulsant Phenobarbital to Julie. Tr. at 105; Pet.Ex. 4, at 235. Julie experienced approximately a total of twelve minutes of seizure activity in the seven days following her third DPT vaccination. Tr. at 109. Julie continued to have seizures throughout the next year. On 12 September 1992, she suffered from a seizure lasting approximately fifty minutes despite being on Phenobarbital medication at the time. Pet.Aff., at 3. Her seizures continue today.

Julie's neurological condition is well documented in the medical records. Thirteen months after Julie's third DPT, Dr. Berebitsky noted on 13 September 1993 that Julie

was "well appearing" and "neurologically intact." Pet.Ex. 2, at 42. It was not until November 1993 that Dr. Berebitsky first noted a problem with Julie's neurological condition. He indicated she had a borderline passing score on the Denver Developmental Screening Test. Pet.Ex. 2, at 45. Julie currently is mentally retarded.

Because Julie had a meningocele lump removed from her skull as a young child, her doctors performed several tests to see if there was any permanent brain damage. These tests were completed prior to her third DPT vaccination and concluded she had no brain abnormalities. She had an MRI scan on 18 May 1992 which reported her brain structure as normal. Pet.Ex. 2, at 174; Tr. at 33. Her lump was checked for cancer, and the test came back reporting there was no cancer. Dr. Manwaring, a board certified pediatric neurosurgeon, did the follow up and he found Julie's pre-immunization neurological condition to be unremarkable except for moderate strabismus. Pet.Ex. 4, at 338. After the vaccination, Julie had MRIs on 21 May 1993 and 13 August 1993 which showed no structural pathology in her brain. Pet.Ex. 2, at 174-76. Dr. Allen Kaplan, the Director of Pediatric Neurology, Phoenix Children's Hospital said in a letter to another doctor the meningocele lump was not the cause of the seizures. Pet.Ex. 4, at 349. Respondent requested Julie undergo two separate genetic workups, on 28 June 1995 and 29 July 1996, and those results were entirely normal. Pet.Ex. 29.

II. FACT WITNESS

In this case, only Dr. Gary Berebitsky was called as a fact witness. It was unnecessary to have other fact witnesses inasmuch as the records speak for themselves, they are not at issue, and additional fact testimony would be redundant.

A. Dr. Gary Berebitsky

Dr. Gary Berebitsky is Julie's primary care physician and a board certified pediatrician. Tr. at 14. He testified that prior to her 10 August 1992 vaccination, Julie was a healthy child except for a small pea-sized meningocele lump in the skull and being cross-eyed. Tr. at 19. She was reaching her developmental milestones and evidenced no seizure activity prior to her third DPT vaccination. Tr. at 19. Finally, Dr. Berebitsky confirmed that the vaccination given to Julie on 10 August 1992 was manufactured by Connaught and had a lot number of 2k31068. Tr. at 24; Pet.Ex. 15.

III. EXPERT WITNESSES

A. Dr. John Menkes[3]

Dr. John Menkes testified on behalf of the petitioner as an expert witness. He is board certified in pediatrics

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[3] Dr. Menkes received his A.B. from the University of Southern California in 1947, his M.S. from the University of Southern California in 1951, and his M.D. from Johns Hopkins University School of Medicine in 1952. He completed his internship at Children's Medical Center, Boston, Massachusetts in 1954 and his residency in pediatric neurology at the

and neurology. He is also a consultant for the Committee on Adverse Vaccine Reactions for the Institute of Medicine. Tr. at 59. He opined that to a reasonable degree of medical probability, the pertussis vaccine triggered a seizure disorder that has proved resistant to medical therapy and this has caused progressive intellectual deterioration in Julie. Tr. at 37-38. He defined an encephalopathy as an "altered abnormal state of the brain." Tr. at 38. He explained the significance of the National Childhood Encephalopathy Study (NCES), which establishes an association between the pertussis vaccine and encephalopathy, and opined that Julie would have been included in the parameters of the study because she had a "complicated seizure" which occurred within seven days of the vaccination. Tr. at 40-41; 93. The complicated seizure is apparent because she required hospitalization. Tr. at 42. On cross-examination, he admitted he did not know that the test subjects in the NCES had to have seizures totaling more than thirty minutes within seven days of the vaccination to be included in the study. Tr. at 75-76.

Next, Dr. Menkes discussed how different vaccine lots can vary up to forty-fold in immunogenicity or in effectiveness of inducing an immune response in the recipient. Tr. at 42. Some batches have far greater adverse effects and neurological symptoms than other batches. Tr.

Neurological Institute of New York, Columbia-Presbyterian Medical Center in 1960. He has served as Associate Professor of Pediatrics at Johns Hopkins and Professor of Neurology and Pediatrics at UCLA. He is board certified in pediatrics and neurology. His *curriculum vitae* lists 124 publications to his credit. His name appears in numerous places as a contributor to the IOM reports.

at 43. The neurological reactions are a result of the pertussis toxin in the whole-cell vaccine. Tr. at 44. He explained that the pertussis toxin couples to G proteins. G proteins are found within a cell and are instrumental in initiating inter and intra-cellular signals. The toxin alters the G proteins and their signals within a cell and from one nerve cell to another. Tr. at 44. The pertussis toxin causes the cells to confuse inhibitory signals with accentuating signals. Tr. at 45. The result is the nerve cells do not signal properly. Tr. at 45. As a result of the pertussis toxin in the brain cells, the inhibitory cells are depressed and the excitatory impulses are enhanced. Tr. at 51. Since the brain functions by electrical signals from one cell to another, the pertussis toxin coupling with the G proteins causes damage to the functioning of the brain. Tr. at 51. The brain's nerve cells begin to stimulate themselves to death. Tr. at 53. This can cause a seizure disorder and encephalopathy. Tr. at 50. Tests done on animals have unequivocally shown that pertussis toxins couple with G proteins. Tr. at 44. In fact, this is such a predictable and verifiable reaction that pertussis toxin is now commonly used in a number of studies that are primarily designed to elucidate this inter and intra-cellular signaling system. Tr. at 45. This medical theory is supported by nerve cell preparations, tissue slices, cellular suspensions, and several hundred medical articles, Tr. at 45, and has been established beyond any contention. Tr. at 49. However, on cross-examination, Dr. Menkes admitted that the theory that the pertussis toxin can cause a seizure disorder with a potential evolution to retardation is not generally accepted in the medical community. Tr. at 79. He speculated that a paper advancing the theory could be

published in Europe. Tr. at 80. He believed that about twenty percent of American pediatric neurologists would concur with the theory and that older pediatric neurologists are more likely to agree with the theory than younger pediatric neurologists. Tr. at 82.

Dr. Menkes testified that once a person has a seizure, a subsequent seizure becomes more likely. The brain remembers having a seizure and it becomes easier and easier for it to have another seizure. This process is called "kindling" other seizures. Tr. at 50. Dr. Menkes explained that a seizure disorder caused by a vaccine is intractable and not easily cured by anti-convulsants (which is unique since only one-half to one percent of seizures are intractable and persistent). Tr. at 63. Seizures caused by pertussis toxin occur shortly after vaccination and are afebrile. Tr. at 63. The child must be normal prior to the vaccination in order to implicate the pertussis toxin. Tr. at 63.

Normally, according to Dr. Menkes, a protective system called the blood-brain barrier keeps toxins out of the brain. Tr. at 45. The pertussis toxin is able to enter the brains of young children (under 6 months) because the blood-brain barrier is not yet operative. Also, the development of the blood-brain barrier may be delayed in some infants. Tr. at 46. This has been established by evidence that most new born children have bilirubin (the normal degenerative product of red cells) in the brain. This causes yellow jaundice, but is not serious unless excessive bilirubin gets into the brain. When the child gets older, the blood-brain barrier matures and bilirubin no longer can pass into the brain. Tr. at 47. In addition, the pertussis toxin can also enter the brain of a young

child with a developed blood-brain barrier because of the anti-toxins in the vaccine. These anti-toxins, or a bacterial infection, can lower the blood-brain barrier through a process called pinocytosis[4] and allow the pertussis toxin to enter the brain even though the child has a developed blood-brain barrier. Tr. at 47.

Dr. Menkes' testimony then focused on Julie's particular case. He opined to a reasonable degree of medical probability that the pertussis toxin breached the blood-brain barrier and got into Julie's brain. Tr. at 49. He did admit, on cross-examination, that with the current state of medical technology, there is no way of knowing for certain if the pertussis toxin got into Julie's brain. Tr. at 86. Presently, there is not a clinical test to see if the toxin had breached the blood-brain barrier. Tr. at 86. He said the fact that she was given a vaccine from a lot with over two hundred reported adverse reactions, including four deaths, gives weight to his conclusion. Tr. at 49. According to Dr. Menkes, Julie did not react to her first or second whole-cell pertussis vaccinations because they were probably from a different lot, Tr. at 88, and she did not react to her fourth vaccination because it was an acellular pertussis vaccine. Tr. at 88. Once Julie had one seizure, she became susceptible to another seizure and this resulted in a seizure disorder. Tr. at 50. The fact that Julie had a normal EEG prior to the vaccine, and then

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[4] Pinocytosis is "the imbibition of liquids by cells, especially the mechanism by which cells ingest extracellular fluid and its contents. . . . it is thought to be a method of active transport across the cell membrane." *Dorland's Illustrated Medical Dictionary* 1296-97 (27th ed. 1988).

showed a deterioration over time in her EEGs supports his theory. Tr. at 52. In addition, the fact that Julie's seizures are intractable, afebrile, and started shortly after the vaccination also lends support to Dr. Menkes' conclusions. Tr. at 63. Finally, the meningocele lump Julie had on the occipital area of her skull is unassociated with any seizures or any other abnormality and is not diagnostically significant in this case. Tr. at 58-59.

In the NCES study in England, subjects had to meet the criteria of at least one of the categories for inclusion in the study. Dr. Menkes believes Julie would have been included in the NCES seizure study because she meets the criteria of having "complicated" seizures. She has complicated seizures because they are afebrile, Tr. at 95, and recurrent. Tr. at 96. Dr. Menkes also believed Julie might have been included through the criteria of having seizures for more than thirty minutes, even though she in-fact only had twelve minutes of seizure activity seven days after vaccination, because the reason Julie did not seize for more than thirty minutes within seven days of the vaccination is because she was taking anti-convulsants. Tr. at 91, 168.

Dr. Menkes opined that Julie does not meet the new table criteria for an encephalopathy. Tr. at 65. However, Dr. Menkes stated Julie has an encephalopathy because she has an altered state of brain function. Tr. at 65. The new table definition of encephalopathy is too restricted. Tr. at 70. The word encephalopathy means "diseased brain." Tr. at 67. A majority of pediatric neurologists would agree with him that a chronic seizure disorder fulfills that definition. Tr. at 67. In Julie's case, the encephalopathy started with one seizure (as the first sign

or symptom) and each succeeding seizure caused a continuing disruption until it evolved into an encephalopathy. Tr. at 65. This explains her global developmental delay and retardation. Tr. at 77. On cross-examination, Dr. Menkes admitted Julie would not have been included in the NCES encephalopathy study because she did not have changes in alertness within seven days of the vaccination. Tr. at 78.

B. Dr. Robert Baumann[5]

Dr. Robert Baumann was called to testify by respondent as an expert witness. He is board certified in pediatrics and neurology. He opined to a reasonable degree of medical certainty that Julie's seizure disorder is unrelated to the immunization. Tr. at 112-13. He believes Julie had an underlying anomaly, manifested in the meningocele lump, that caused her current condition. Tr. at 113. In addition, Julie's seizures were brief and she was not encephalopathic during the period of the seizures. This is not what a doctor would expect if her illness was caused by a toxin. Tr. at 113. Her EEGs showed no abnormalities until she was 15 months of age. Tr. at 114.

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[5] Dr. Baumann received his B.S. from Tufts University, Medford, Massachusetts in 1961 and his M.D. from Western Reserve University, Cleveland, Ohio in 1965. He completed his internship at the Department of Pediatrics, University of Chicago in 1966 and his residency at the Department of Pediatrics, University of Chicago in 1967. He is currently a Professor of Neurology and Pediatrics at the University of Kentucky. He is board certified in pediatrics, psychiatry and neurology, and epidemiology. His *curriculum vitae* lists 48 publications to his credit.

According to Dr. Baumann, Julie would not have been included in the NCES study because she does not meet the operational criteria of the study. Tr. at 114. She did not met the requirement of having in excess of thirty minutes of seizures within seven days of vaccination. He said that "complicated seizures" were not a criteria used for including children in the study. Tr. at 115. Also, even if "complicated seizures" were a criteria, the term is too vague to mean anything. Tr. at 115.

Dr. Baumann testified that the vast majority of the scientific community agrees with the Institute of Medicine's position[6] that an encephalopathy can be the sequela to an immunization of DPT. Tr. at 116-17. However, Julie did not suffer an acute encephalopathy as a result of her third DPT. Tr. at 119. The medical records are clear she did not have a clouded level of consciousness. Between her seizures she was awake, alert, appropriate, and fed. Tr. at 120. She may have a chronic encephalopathy today. Tr. at 120.

Dr. Baumann believes Julie's seizures are not a result of her immunization. Instead, she has a cognitive disorder that developed *in utero*. Tr. at 122. The meningocele lump was the first manifestation of the cognitive disorder and the subsequent manifestations are the seizures and her current diminished capacity. Tr. at 22. He acknowledges that Julie had an MRI after the surgery to remove the lump and another follow up MRI one year later and both of those MRIs showed Julie to be normal, but he

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[6] The conclusions of the IOM are contained in the "DISCUSSION" section, *infra*.

does not believe this contradicts his opinion because a lot of children with normal MRIs later develop seizures. Tr. at 128. In light of her underlying disorder, it is normal for a child with a meningocele to behave normally until six months of age but later develop symptoms of developmental delay. Tr. at 129. The vaccination did not significantly aggravate her condition because it is normal for Julie to show a gradual deterioration in her EEGs. Tr. at 130. However, Dr. Baumann was not aware of any studies that show what percentage of children with a meningocele later experience seizures or developmental delay. Tr. at 133. Lastly, Dr. Baumann did not believe it was medically relevant that the particular vaccine batch given to Julie had more adverse reactions than other batches. Tr. at 138.

On cross-examination, Dr. Baumann readily agreed that the underlying abnormality he opines caused the meningocele lump, seizures, and developmental delay cannot be demonstrated on an MRI, or by any chemical test, or visualized by any radiographic technique, may not show up in an autopsy, and in fact does not even have a specific name. Tr. at 139-42. Also, the lump is made up of the meningeal material that covers the brain. It is not composed of brain cell material. Tr. at 149. All of the articles submitted by the doctor say the pathogenesis of meningoceles are unknown. Tr. at 151. He said neurology is mostly unknown causes. Tr. at 151. He refers to the disease as an "underlying anomaly" that is unknown, but he refused to call the disease idiopathic. Tr. at 160-61.

Dr. Baumann said petitioner's expert, Dr. Menkes, "gave the most lucid presentation I have ever heard. A

first rate presentation. And yet, I think even with a presentation of that quality, I think over eighty percent would think it's a[n un]tenable hypothesis." Tr. at 118. Dr. Baumann was not familiar with the literature on the use of pertussis toxin to produce certain electrical signals in the brain, but said "if Dr. Menkes tells me you can use this experimentally, I'm sure that's quite true." Tr. at 144.

IV. STATUTORY REQUIREMENTS

The Vaccine Act permits establishment of causation in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. The Vaccine Injury Table lists specific vaccines and certain injuries or conditions that may occur as a result of a vaccine's administration. If the onset of those injuries or conditions is found to occur within a prescribed time period, a rebuttable presumption is created that the vaccine caused the condition.[7]

In the case at bar, petitioner alleges her third DPT, administered on 10 August 1992, caused her residual seizure disorder and encephalopathy. Inasmuch as RSD is an injury not listed in the new Vaccine Table,[8] petitioner's

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[7] Section 11(c)(1)(C)(i); section 14(a).

[8] Under the change in the regulations, 42 C.F.R. §§ 100.1-100.3 (1995), effective 10 March 1995, petitioners who file on that date or later must comply with the new Vaccine Table. The new Vaccine Table no longer lists RSD as a table injury and the definition of an encephalopathy has become more demanding.

thesis under the Act is one of causation-in-fact. Encephalopathy is still a table-injury. However, petitioner concedes she does not meet the criteria of an onset of an encephalopathy as defined in the new Vaccine Table[9] and thus her thesis again is one of causation-in-fact.

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[9] The applicable provisions of 42 C.F.R. 100.3 state:

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table. . . .

* * *

(2) *Encephalopathy.* For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization. . . .

(A) Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

* * *

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . :

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

Causation-in-fact is an acceptable thesis under the Act. Petitioner may establish entitlement to an award through traditional tort methods. Causation-in-fact cases include injuries not listed on the Table or injuries that are listed but occurred outside the temporal parameters of the Table. Entitlement in such cases is dependent upon proof by a preponderance of the evidence that the vaccine actually caused the injury.

Causation-in-fact delves directly into the continuing controversy of whether the DPT vaccine can cause permanent neurological disorders. Thus, a petitioner's prima facie case is more difficult to establish. Not only is proof of injury necessary but petitioner also bears the burden of linking the injury directly to the vaccine. Ruling out other potential causes is an essential element but does not itself establish causation. Thus, the proffered theory of causation must not only be shown to be possible but also must be shown to have occurred in this particular case.

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(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3 (1995).

It should be noted that in analyzing a contention of causation-in-fact, the presumptions available under the Vaccine Injury Table are inoperative. The burden rests on the petitioner to show that the vaccination in question more likely than not caused the specific injury, *under the same standards which apply in traditional tort litigation*, in which the same "preponderance of the evidence" standard applies. *Hines v. Secretary of the DHHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The preponderance of the evidence standard requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before (he) may find in favor of the party who has the burden to persuade the (judge) of the fact's existence." *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. James, *Civil Procedure* 250-51 (1965)). Mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl.Ct. 476, 486 (1984).

The Federal Circuit in Grant v. Secretary of the DHHS, 956 F.2d 1144 (Fed. Cir. 1992) summarized the legal criteria required to prove causation-in-fact under the Vaccine Act. The court noted that a petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing the vaccination was the reason for the injury. A *reputable medical or scientific explanation* must support this logical sequence of cause and effect.

Id. at 1148 (citations omitted) (emphasis added); *see also Hines v. Secretary of the DHHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 370 (1990); *Carter v. Secretary of the DHHS*, 21 Cl. Ct. 651, 654 (1990); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989); *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983). Temporal association alone is *not* sufficient. *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 370 (1990). "Similarity of petitioner's injury to injuries listed on the Table does not show causation in fact. Encephalitis, seizure disorders, and other Table injuries can have causes other than administration of a vaccine." *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 370 (1990). Moreover, in an off-Table case, where the injury or death in question is idiopathic, and no cause can be determined, the petitioners' claim must fail. *Hines v. Secretary of the DHHS*, 21 Cl. Ct. 634, 650 (1990), *aff'd*, 940 F.2d 1518 (Fed. Cir. 1991).

To support a causation-in-fact allegation, petitioner's expert must do more than suggest a possible correlation based on a temporal relationship between vaccination and the injury; he must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370. If petitioner's expert views the temporal relationship as "key," the claim must fail. *Thibaudeau v. Secretary of the DHHS*, 24 Cl. Ct. 400, 403 (1991).

A reputable medical or scientific explanation does not simply mean, however, any theory that a medical expert is willing to espouse. In construing the Federal Rules of Evidence, the Supreme Court recently held that it is the trial judge's responsibility to ensure that "any and all scientific testimony or evidence admitted is not

only relevant, but reliable." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2795 (1993); *see also* Vaccine Rule 8(b) (the trier of fact is obliged to consider "all relevant, reliable evidence."). Rule 702 provides that an expert witness may testify to his "scientific, technical, or other specialized knowledge." The term "knowledge," however, "connotes more than subjective belief or unsupported speculation." *Daubert*, 113 S.Ct. at 2795. Thus, the expert's proposition must have been "derived by the scientific method." *Id.* This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993). Factors relevant to that determination may include, but are not limited to:

> whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Id; see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2796-97 (1993). The overall touchstone is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

Other prerequisites to compensation include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the

administration of the vaccine, § 11(c)(1)(D)(i); (2) that the petitioner incurred in excess of $1000 in unreimbursable vaccine-related expenses, § 11(c)(1)(D)(i); (3) that the vaccine was administered in the United States, § 11(c)(1)(B)(i)(1); (4) that the petitioner did not previously collect a judgment or settlement in a prior civil action, § 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative, § 11(b)(1)(A).

V. DISCUSSION

In assessing any inconsistencies between medical records and oral testimony, the undersigned first looks to the issue of the credibility of the fact witnesses. The undersigned thoughtfully observed the demeanor, comportment and presentment of Dr. Gary Berebitsky and has concluded he is a credible witness. Any inconsistencies between his testimony and the medical records are at worst *de minimus*.[10] This is a case where the medical facts are not greatly in dispute.

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[10] The following standard has been applied when testimony is *in conflict* with medical records:

> It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight. *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947); *Montgomery Coca-Cola Bottling Co. v. United States*, 615 F.2d 1318, 1328 (Ct. Cl. 1980); *see also* 32A C.J.S. *Evidence* § 1033 (1964). That rule has been followed in Program cases. *See, e.g., Flynn v. Secretary of HHS*, No. 89-54V, 1990 WL 293364 (Cl. Ct. Spec. Mstr. May 17, 1990). The rule should not be applied blindly, however. Written records which are, themselves,

In the case at bar, petitioner alleges her third DPT, administered on 10 August 1992, caused her residual seizure disorder and encephalopathy. Inasmuch as residual seizure disorder is an injury not listed in the new Vaccine Table,[11] petitioner's thesis under the Act is one of causation-in-fact. Encephalopathy is still a table-injury. However, petitioner concedes she does not meet the criteria of an onset of an encephalopathy as defined in the new Vaccine Table[12] and thus her thesis again is one of causation-in-fact. The analysis in this matter divides into the following three queries: (1) Does Julie suffer from a seizure disorder and/or chronic encephalopathy? (2) Can pertussis toxin/dpt cause a seizure disorder and/or chronic encephalopathy? And (3), did pertussis toxin/dpt in this case cause Julie's seizure disorder and/or chronic encephalopathy?

> inconsistent, should be accorded less deference than those which are internally consistent. Records which are incomplete may be entitled to less weight than records which are complete. . . . Further, it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant. *See Clark v. Secretary of HHS*, No. 90-45V, 1991 WL 57051 (Cl. Ct. Spec. Mstr. Mar. 28, 1991).

Murphy v. Secretary of HHS, 23 Cl. Ct. 726, 733 (1991).

[11] *See* footnote 8.

[12] *See* footnote 9.

A. Diagnosis: Does Julie suffer from a seizure disorder and/or chronic encephalopathy?

Petitioner contends that Julie suffers from a seizure disorder. Julie had her first seizure, lasting about seven seconds, the day after her third DPT. The next day she experienced four seizures lasting each about one minute and was rushed to the hospital. The following day, she had a five and one-half minute seizure in the hospital. About one month later, she suffered from a seizure lasting approximately fifty minutes despite being on Phenobarbital. She continued to have seizures throughout the next year. Her seizures continue today. The court finds, by a preponderance of the evidence, that Julie suffers from a seizure disorder.

Petitioner also contends that Julie suffers from an encephalopathy. Withal, petitioner concedes that she does not meet the criteria of an onset of an encephalopathy under the new Vaccine Table. The new Vaccine Table gives very precise criteria which petitioners must meet. Because the petitioner concedes she does not meet the criteria of the new table, she must proceed with causation-in-fact for an off-table injury. The relevant statutory language states the petitioner may recover if the petitioner sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine. § 11(c)(1)(C)(ii)(II). The petitioner can recover for any illness caused by the vaccination. Unless otherwise defined, "the words of a statute must be given their usual and ordinary meaning." *State v. Thiele*, 736 P.2d 297, 301 (Wash.Ct.App. 1987). The statute does not define what

constitutes an "illness" or an off-table encephalopathy. Petitioner's expert medical doctor defined an encephalopathy as a "diseased brain" or "an altered state of brain function." Tr. at 65, 67. Respondent's expert medical doctor defined an encephalopathy as a "clouded level of consciousness." Tr. at 120. An encephalopathy is "any degenerative disease of the brain." *The Sloane-Dorland Annotated Medical-Legal Dictionary* 250 (1987); *Dorland's Illustrated Medical Dictionary* 550 (27th ed. 1988). Julie's treating pediatrician, Dr. Berebitsky, has diagnosed Julie with an encephalopathy.[13] Petitioner's expert medical doctor opined that Julie has an encephalopathy. Respondent's expert medical doctor opined that Julie did not have an acute encephalopathy at the time of the first seizures, but today she has a chronic encephalopathy. Currently, Julie is mentally retarded and developmentally delayed. The court finds, by a preponderance of the evidence, that Julie suffers today from a chronic encephalopathy.

B. Theory of Causation: Can pertussis toxin/dpt cause a seizure disorder and/or chronic encephalopathy?

Having established that Julie suffers from a seizure disorder and an encephalopathy, the next issue to be

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[13] Because of the personal contact between physician and patient, as a general rule the court gives greater weight to treating doctors than to those whose evaluation is limited to a review of the records in anticipation of a hearing. *See, e.g., Bastian v. Secretary of HHS*, No. 90-1161V, 1994 WL 551465 (Fed. Cl. Spec. Mstr. Sept. 22, 1994).

decided is whether the DPT vaccination of 10 August 1992 actually caused Julie's current condition. That determination requires the court to decide whether pertussis toxin/dpt can cause a seizure disorder and/or chronic encephalopathy. The undersigned responds in the affirmative.

The Act establishing this Program charged the Institute of Medicine (IOM) of the National Academy of Sciences to review the medical and scientific literature on possible adverse consequences of pertussis and rubella vaccines and to prepare a report on the results of its review. A committee was formed, conducted the review, and published its report: Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* (Nat'l Academy Press 1991) (hereinafter 1991 IOM Report). The Act likewise mandated a periodic review of possible adverse events associated with DPT vaccination. The next committee's report was published in 1994: Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (Nat'l Academy Press 1994) (hereinafter 1994 IOM Report).[14]

Considering the charge given to the IOM and the scope of its review, the court considers its conclusions to be authoritative on the issue and subject to great deference in this Program.

The 1991 IOM report concludes "(a) that the evidence indicated a causal relation between DPT and *febrile* seizures, (b) that the evidence *did not indicate* a causal relation between DPT and *afebrile* seizures." Institute of

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[14] Pet.Exh. 26.

Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* 3 (Nat'l Academy Press 1994) (summarizing 1991 IOM report) (emphasis added). The 1994 IOM report examined the relationship between DPT and chronic nervous system dysfunction (an encephalopathy and seizure disorder in Julie's case). It concluded:

> that the *balance of evidence is consistent with* a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccination. . . . *The evidence remains insufficient to indicate* the presence or absence of a causal relation between DPT and chronic nervous system dysfunction under any other circumstances. That is, because the NCES is the only systematic study of chronic nervous system dysfunction after DPT, the committee can only comment on the causal relation between DPT and those chronic nervous system dysfunctions under the conditions studied by the NCES. In particular, it should be noted that the chronic nervous system dysfunctions associated with DPT followed a serious acute neurological illness that occurred in children within 7 days after receiving DPT.

Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* 15-16 (Nat'l Academy Press 1994) (emphasis in original). The undersigned concludes that the 1991 & 1994 IOM reports establish, by a preponderance of the evidence, that DPT can cause acute *febrile* seizures within seven days of vaccination,[15] but

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[15] "*Febrile* seizures are the single most common adverse reaction to pertussis immunization." Gerald M. Fenichel,

there is an insufficiency of scientific evidence to conclude that DPT can cause *afebrile* seizures, and DPT can cause chronic nervous system dysfunctions (seizure disorders and encephalopathy) in cases which met the criteria established by the NCES.[16] The National Childhood Encephalopathy Study[17] is a comprehensive epidemiological study done in the United Kingdom finding statistically significant risk for neurological injury for up to seven days following a DPT vaccination. The criteria of the NCES requires the child to have an acute encephalopathy, or at least thirty minutes of seizure activity within seven days of the vaccination, or to have "complicated" seizures. The parties debated vigorously over the meaning of the word "complicated" seizures. The evidence in this case requires this court to conclude that the term "complicated" is shorthand for a longer phrase used in other places in the NCES study. Ergo, the term "complicated" means complicated "by [a] coma lasting 2 hours or more, or followed by paralysis, or other neurological signs not previously present, lasting 24 hours or more."

Clinical Pediatric Neurology: A Signs and Symptoms Approach 62 (3rd ed. 1997).

[16] The conclusion of this court is in accordance with the following cases: *Elsener v. Secretary of the DHHS*, No. 90-3361V, at 7-8 (Fed.Cl.Spec.Mstr. Oct. 30, 1997(unpublished); *McMurry v. Secretary of the DHHS*, No. 95-682V, 1997 WL 402407, at * 5 (Fed.Cl.Spec.Mstr. June 27, 1997).

[17] R. Alderslade et al., *United Kingdom Department of Health and Social Security, Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccine and Immunization, The National Childhood Encephalopathy Study* 79-184 (Her Majesty's Stationary Office 1981); Resp.Exh. 1.

R. Alderslade et al., *The National Childhood Encephalopathy Study* 146-47, 157 (Her Majesty's Stationary Office 1981).

In the case at bar, petitioner proffered an additional theory of causation slightly different from that enumerated in the 1991 & 1994 IOM reports. While the court accepts the theory of causation proffered in the 1991 & 1994 IOM reports, the court does not find, by a preponderance of the evidence, that the theory of causation proffered by petitioner meets the standards of scientific reliability enunciated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2795 (1993).[18] There are four factors listed in *Daubert* as guideposts for this court to follow to determine if a scientific theory is reliable. The four factors are (1) general acceptance in the scientific

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[18] The theory of causation proffered by petitioner was not accepted as reliable by the United States Court of Federal Claims in the case of *Mobley v. Secretary of the DHHS*, 22 Cl.Ct. 423, 429 n. 9 (1991). In that case, Dr. Kinsbourne testified:

> The best available information is that the pertussis vaccine contains two agents which singly or, more probably, in conjunction can in occasional or rare cases be severely damaging to brain cells and damage them permanently. And these are the pertussis toxin and the pertussis endotoxin, which is also described as a lipopolysaccharide. Now, it has been shown by chemical studies that if pertussis toxin is allowed to come into contact with neurons, the basic cells that do the work of the brain, then, that toxin is capable of interfering with the neuron's energy metabolism.

Id; cf. Misenko v. Secretary of the DHHS, No. 92-0013V, 1995 WL 761436, at * 15 (Fed.Cl.Spec.Mstr. Dec. 7, 1995) (Special Master found pertussis toxin and endotoxin results in low blood pressure and hypoglycemia which ultimately causes an encephalopathy).

community; (2) whether it's been subjected to peer review and publication; (3) whether it can and has been tested; (4) and whether the known potential rate of error is acceptable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993).[19] In the case at bar, petitioner's theory, as explained by Dr. Menkes, is that the pertussis toxin in the DPT vaccine is able to breach the blood-brain barrier in a child either because the barrier is underdeveloped in infancy or because of endotoxins in the pertussis toxin. Once in the brain, the pertussis toxin causes the nerve cells to fire erratically and results in an afebrile seizure. The first seizure causes more seizures and the result is a seizure disorder and an encephalopathy.

Examined in the light of the four guideposts enumerated in *Daubert*, the court must conclude that petitioner's theory of causation is not based on reliable scientific evidence. First, petitioner's theory is not generally accepted in the scientific community, as admitted by both Dr. Menkes and Dr. Baumann. Tr. at 79, 118. Second, the theory has not been subjected to peer review publication because Dr. Menkes said it is not generally accepted and would not get published in the United States. Tr. at 79. Third, the theory has not been satisfactorily tested. Finally, the error rate of the tests is not known at all (because of the lack of test results).

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[19] These four factors come from the *Daubert* block quotation on page 10 of this decision.

For these reasons, the undersigned concludes that the preponderance of the evidence supports the IOM conclusion that a causal relationship exists between DPT and acute *febrile* seizures within seven days of DPT vaccination, but not *afebrile* seizures. Also, a causal relationship exists between DPT and chronic nervous system dysfunctions (encephalopathy and seizure disorders) in cases which met the criteria established by the NCES.[20] A petitioner can satisfy the criteria established by the NCES by meeting the requirements of any one of the three categories for inclusion in the study. The injured child, within seven days of vaccination, must either: (1) experience an acute encephalopathy, defined as an "altered level of consciousness, confusion, irritability, [or] changes in behaviour," R. Alderslade et al., *The National Childhood Encephalopathy Study* 157 (Her Majesty's Stationary Office 1981); or (2) have more than thirty minutes of seizure

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[20] Petitioner also advanced the theory that Julie's injuries were a result of the administration of a vaccine from a "hot lot" that had a history of causing injuries in children. Julie was given a vaccination manufactured by Connaught that had a lot number of 2k31068. Petitioner submitted four articles on the batch-to-batch variability of DPT vaccines. Pet.Exhs. 34-37. Petitioner also submitted the FDA adverse reaction file in reference to lot number 2k31068. Pet.Exh 14. It showed that there have been 22 serious, including 4 fatal,'injuries reported to have occurred in conjunction with the administration of the vaccine lot given to Julie. However, presumably, there are random adverse reactions unrelated to the administration of a vaccine with every batch of several thousand vaccines. While the court finds this probative evidence to weigh heavily in favor of petitioner's claim, it does not find the evidence to be determinative of the issue because it is too conjectural as to this specific immunization.

activity, *id*; or (3) have seizures complicated by a coma lasting two hours or more, or followed by paralysis, or other neurological signs not previously present, lasting twenty-four hours or more. *Id.*

C. Application of Theory: Did pertussis toxin/dpt in this case cause Julie's seizure disorder and/or chronic encephalopathy?

Having found that it is medically possible for DPT to cause a seizure disorder and encephalopathy, the final query is whether DPT caused Julie's seizure disorder and/or encephalopathy in this particular case. The undersigned responds in the negative.

The 1991 IOM report concludes that DPT can cause febrile, but not afebrile seizures. Julie's seizures immediately after the vaccination were afebrile. Since her first seizures were not febrile, there is a lack of evidence to conclude that Julie's initial seizures were caused in fact by her DPT vaccination.

This court must also conclude that Julie's seizure disorder and encephalopathy were not caused-in-fact by her third DPT vaccination because she does not meet even one of the three criteria of the NCES. The 1994 IOM report which concludes that DPT can cause chronic nervous system dysfunction expressly states the conclusion is only valid in cases which met the NCES criteria.[21] The criteria for the NCES study were cases where the child had (1) an acute encephalopathy, as defined by the NCES,

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[21] *See* block quote from the 1994 1OM report on page 13-14 of this decision.

or (2) at least thirty minutes of seizures, or (3) had seizures "complicated" by a coma lasting two hours or more or followed by paralysis or other neurological signs not previously present, lasting twenty-four hours or more. In Julie's case, she did not have an acute encephalopathy following her DPT vaccination. Julie did not exhibit the "altered level of consciousness" required by the NCES. In fact, Julie was alert and active in the ambulance and hospital. Petitioner's expert medical doctor admitted that Julie would not have been included in the NCES encephalopathy study. In addition, Julie only had twelve minutes of seizure activity within seven days of her vaccination. This is far short of the thirty minute NCES requirement. It is too speculative to conclude that absent the Phenobarbital Julie's seizures would have lasted more than thirty minutes. Finally, Julie didn't have a "complicated" seizure because she didn't lapse into a coma after her vaccination, nor exhibit any paralysis. To the contrary, after her first seizure, Julie was alert and active in the ambulance and hospital and played with her oxygen mask in the ambulance. Because Julie does not meet the criteria of even the NCES, the court concludes that petitioner has failed to prove by a preponderance of the evidence that Julie's injuries were caused-in-fact by her third DPT vaccination of 10 August 1992.[22]

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[22] Since this court has already ruled that petitioner has not met the requirements of § 13(a)(1)(A), it is unnecessary to determine if she also meets the "factor unrelated" requirements of § 13(a)(1)(B), but a little *dicta* never hurt anyone. This court concludes that there is not a preponderance of the evidence to prove that Julie's seizure disorder or encephalopathy is due to any factor unrelated to the administration of the vaccine. Section 13(a)(1)(B) states:

VI. CONCLUSION

1. As the parent of her minor daughter, petitioner has the requisite capacity to bring this action. Section 11(b)(1)(A); Pet.Exh. A, at 1.

2. Petitioner has not previously collected an award or settlement of a civil action in connection with Julie's

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> compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole – (b) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.
>
> * * *
>
> (2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine" –
>
> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.

§ 13(a)(1)(B) & (2)(A). This court can not think of a better example of an idiopathic disease then the one proffered by respondent. Respondent's "underlying disorder" cannot be observed chemically, radiographically, electrically, genetically, or even visually upon death. The disorder doesn't even have a name (in an age when every malady of the human condition has a name – *e.g.* "road rage disorder"). The proffered disease meets the Greek definition of the word which is "hidden." For these reasons, this court concludes that Julie's injuries were not caused by a factor unrelated, and even if they were, the disease proffered by respondent is idiopathic and *ergo* insufficient as a matter of law. It is important to note that this court does not draw any conclusions about the actual etiology of Julie's injuries because the court was not presented with sufficient evidence to form a conclusion.

alleged vaccine-related injury. Section 11(c)(1)(E); Pet.Exh. A, at 4.

3. Julie was administered a vaccine listed in the Vaccine Injury Table. Section 11(c)(1)(B)(i)(I); Pet.Exh. A, at 2.

4. Said vaccine was administered in the United States. Section 11(c)(1)(B)(i)(I); Pet.Exh. A, at 2.

5. There is a preponderance of the evidence that Julie suffered the residual effects of her alleged injury for more than 6 months after the administration of the vaccine. Section 11(c)(1)(D)(i); Pet.Exh. A to Pet.Exh. 37.

6. There is a preponderance of the evidence that petitioner incurred unreimbursable expenses due in whole or in part to such injury in an amount greater than $1,000. Section 11(c)(1)(D)(i); Pet.Exh. A, at 3-4.

7. There is not a preponderance of the evidence that Julie's 10 August 1992 DPT vaccination caused-in-fact her seizure disorder or encephalopathy.

Based on the foregoing, the undersigned finds that petitioner is not entitled to compensation in this case. In the absence of a motion for review[23] filed pursuant to RCFC Appendix J, the clerk of court is directed to enter judgment dismissing this case with prejudice.

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[23] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review.

IT IS SO ORDERED.

/s/ Richard B. Abell
Richard B. Abell
Special Master

United States Court of Appeals for the Federal Circuit

98-5161

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

ORDER

(Filed Feb. 2, 2000)

A combined petition for rehearing and petition for rehearing en banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on February 9, 2000.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: February 2, 2000

cc: Andrew W. Dodd
Vincent J. Matanoski

TERRAN V HHS, 98-5161
(CFC – 95-VV-451)

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public order.

APPELLANT'S MOTION FOR RECALL AND STAY OF THE MANDATE PENDING THE FILING OF A PETITION FOR WRIT OF CERTIORARI

(Filed Feb. 29, 2000)

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 98-5161

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor

Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES

Respondent-Appellee.

On Appeal from the United States Court of Federal Claims in 95-VV-451, Judge Moody R. Tidwell

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(Filed Mar. 6, 2000)

[GRANTED.

FOR THE COURT,

MAR – 6 2000
Date

/s/ Jan Horbaly
JAN HORBALY
Clerk]

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TERRAN v. SECRETARY OF HHS

No. 98-5161

Certificate of Interest

Counsel for the appellant certifies the following:

1. The full name of every party represented by me is Michele Y. Terran, as legal representative of Julie F. Terran, a minor.

2. The names of the real parties in interest represented by are set forth in item 1, immediately preceding.

3. The parent companies, subsidiaries, and affiliates that have issued shares to the public, of the party or amicus curiae represented by me are: none.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

Law Firm	Attorney
Andrew W. Dodd A Professional Corporation	Andrew W. Dodd
Cooper, Carvin & Rosenthal	Robert J. Cynkar Rachel L. Brand

February 29, 2000

Respectfully submitted,

/s/ Andrew W. Dodd by Robert J Cynkar
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Counsel for Petitioner/Appellant

APPELLANT'S MOTION FOR RECALL AND STAY OF THE MANDATE PENDING THE FILING OF A PETITION FOR WRIT OF CERTIORARI

Plaintiff-appellant, Michele Terran, respectfully moves for an order recalling and staying this Court's February 9 mandate pending the timely filing and a disposition of a petition for a writ of certiorari in the United States Supreme Court.

This motion is necessitated by the idiosyncratic interplay of the National Child Vaccine Injury Act ("Vaccine Act") on the one hand, which gives the appellant ninety days from issuance of the mandate to either accept the decision in these proceedings or file suit in state court, with the Rules of the Supreme Court of the United States

on the other hand, which provides the same ninety-day period in which to file a petition for a writ of certiorari. In short, if the mandate is not recalled and stayed, appellant will either be foreclosed from a recourse to state court or from the opportunity to seek Supreme Court review in these proceedings. We respectfully submit that such a choice unfairly prejudices the rights of appellant, and indeed, that Congress did not intend to bar the doors of the Supreme Court in this manner, particularly in a case, such as this one, that raises important constitutional questions.

Background

In this case, Plaintiff instituted a proceeding before a Special Master of the Court of Federal Claims, seeking compensation under the Vaccine Act, 42 U.S.C. §§ 300aa-1 – 34 (1994), for injuries to her minor daughter resulting from administration of a diphtheria-pertussis-tetanus vaccine. The Special Master denied Plaintiff's claim. A panel of this court upheld that decision, ruling that the Vaccine Act's provisions permitting the Secretary of Health and Human Services to amend the Act did not violate the bicameralism or presentment requirements of the Constitution or represent an unconstitutional delegation of legislative power to the executive. This court denied Plaintiff-appellant's petition for rehearing and suggestion for rehearing en banc on February 2, 2000, of which Plaintiff's counsel received notice on February 9. The mandate of this Court issued on the same day, February 9. Issuance of the mandate commenced a ninety-day period in which Plaintiff must elect to accept the decision of the Special Master denying her claim under the

Vaccine Act or reject that decision and file a suit against the vaccine manufacturer in a state or federal court. *See* 42 U.S.C. § 300AA-21(a). At the same time, in conflict with this ninety-day election period under the Vaccine Act, is the ninety-day period during which a petition for a writ of certiorari to the Supreme Court may be filed. *See* SUP. CT. R. 13(1).

Argument

I. The Court Should Recall and Stay Its Mandate

A federal appellate court has clear authority to recall its mandate,[1] and, although mandates are recalled infrequently, a court may do so in order to "protect the integrity of its own processes," to "prevent injustice," in light of "unusual circumstances," or for other "good cause." *Zipfel v. Halliburton Co.*, 861 F.2d 565, 567 (9th Cir. 1988); *see also Bryant v. Ford Motor Co.*, 886 F.2d 1526, 1529 (9th Cir. 1989); *American Iron & Steel Inst. v. EPA*, 560 F.2d 589, 594, 598 (3rd Cir. 1977).

A. There is Good Cause for a Recall and Stay in this Case

There is good cause in this case for recalling the mandate because of the unique conflict it inadvertently

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[1] *See, e.g., Calderon v. Thompson*, 523 U.S. 538, 549 (1998); *United States v. Tolliver*, 116 F.3d 120, 123 (5th Cir. 1997); *Bryant v. Ford Motor Co.*, 886 F.2d 1526, 1529 (9th Cir. 1989); *American Iron & Steel Inst. v. EPA*, 560 F.2d 589, 594 (3rd Cir. 1977) (citing *Reserve Mining Co. v. Lord*, 529 F.2d 181, 184 (8th Cir. 1976); *Powers v. Bethlehem Steel Corp.*, 483 F.2d 963 (1st Cir. 1973)).

creates. Within ninety days, the Plaintiff must effectively end these proceedings by electing either (1) to accept the special master's decision; or (2) to reject it and file a suit in state court. At the same time, Plaintiff's petition for certiorari is due within ninety days of the mandate's issuance. *See* SUP. CT. R. 13(1). This places Plaintiff in an untenable procedural posture: if she chooses to press her appeal to the Supreme Court, she loses her right to go to state court; if, on the other hand, she timely exercises her right to file in state court, this proceeding ends and she cannot seek review by the Supreme Court.

Neither the text nor the legislative history of the Vaccine Act suggests that Congress intended to effectively foreclose Supreme Court review of proceedings under the Act in this way. The Vaccine Act, after all, is constructed to require a vaccine-injured individual to seek recourse first through the special Master system, and then, if that proceeding does not provide satisfactory results, to permit submission of her claim to a court of law. *See* 42 U.S.C. § 300aa-11(a)(2). A recall and stay of the mandate is actually *more* consistent with this framework, for its lets a plaintiff fully pursue proceedings under the Special Master process before turning to what Congress obviously wanted to be a last resort – the filing of a classic tort action.

These reasons for a recall are bolstered by the fact that none of the concerns traditionally counseling against such action are implicated by this case. No hardship will be imposed on any party if the mandate is recalled. The government respondent will not be caused to expend any effort by virtue of the recall except to respond to the subsequent petition for certiorari, which it would have to

do even if the mandate were not recalled and Plaintiff elected not to file in state court within the ninety-day period. Nor will the courts be burdened. To the contrary, recall and stay will merely postpone potential state-court litigation until disposition of the petition for writ of certiorari by the Supreme Court. No court but the Supreme Court is required to take any action until the time of that disposition. Finally, the recall and stay will save the prospective defendant – the vaccine manufacturer – from responding to a lawsuit that might be rendered unnecessary by the Supreme Court's grant of certiorari. Thus, recall serves the Vaccine Act's purpose of sparing vaccine manufacturers from tort litigation by giving those injured by vaccines an alternative avenue for compensation.

No party in this case has "placed heavy reliance" on the issuance of the mandate. *Calderon v. Thompson*, 523 U.S. 538, 552 (1998). This is not a circumstance, such as in *Calderon v. Thompson*, where issuance of the mandate caused a lower court or other governmental agency to take action in reliance on the federal appellate court's decision. *See id.* at 551-53 (following mandate denying habeas petition, state courts and executive agencies proceeded with preparations for defendant's execution). Nor will recall and stay undermine the government's interest in finality of judgments and repose, because Plaintiff does not ask this court to reconsider or modify its ruling. *See id.* Her request for recall and stay of the mandate merely seeks to have the period for election tolled until the Supreme Court rules on her petition for certiorari.

In addition to recall of the mandate, Plaintiff moves the court to stay the mandate for ninety days pending her petition for certiorari. An appellate court may do so

where the plaintiff shows that the petition would present a "substantial question" and where there is "good cause for a stay." FED. R. APP. P. 41(d)(2)(A). In addition, the Supreme Court has held that a motion for stay of the mandate should show that there is a "reasonable probability that certiorari will be granted, . . . a significant possibility that the judgment below will be reversed, and a likelihood of irreparable harm" if the mandate is not stayed; the court should also balance the equities to consider the relative harms to the movant and respondent and to the public interest. *Barnes v. E-Systems, Inc. Group Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1302, 1304-05 (1991) (Scalia J.).

For the same reasons that recall of the mandate is warranted, there is clearly "good cause" for a stay in this case. Moreover, the balance of equities in this case favors staying the mandate. As discussed above, "irreparable harm" to Plaintiff would result from an election not to file in the district court – she would entirely waive any judicial consideration of her claims – and irreparable harm might also result, in the form of needless expenditure of time and resources, if she opts to file while her petition for certiorari is pending. The government as respondent, on the other hand, would not be harmed at all by the stay. And the public interest, far from being harmed, would actually be served by the stay, which would prevent potentially wasteful expenditure of judicial resources and would serve the legislative purpose of shielding vaccine manufacturers from unnecessary tort litigation.

B. This Case Presents Substantial Questions

Plaintiff's petition for certiorari also would present substantial and important questions. First, Plaintiff would argue, as Judge Plager did in dissent, that the Vaccine Act, 42 U.S.C. § 300aa-14(a)(1)-(4), unconstitutionally permits the Secretary of Health and Human Services to amend the law by replacing the statutorily enacted Vaccine Table with another of her own making, in clear violation of the separation of powers. Law-making is the province of the Legislature, and may be effected only through passage of an Act by both houses of Congress and presentment to the President, whose authority in this field is limited to signing or vetoing the Act in its entirety. *See, e.g., Clinton v. City of New York*, 524 U.S. 417 (1998). Moreover, amendment of statutes, no less than their creation, is subject to these constitutional requirements. *See INS v. Chadha*, 462 U.S. 919, 954 (1983). Thus, any statutory modification by the executive, such as the amendment of the Vaccine act undertaken by the Secretary under section 300aa-14(a), violates both the bicameralism provision and the Presentment Clause of the Constitution. This conclusion is mandated not only by a plain reading of the Constitution's text, but by the Supreme Court's recent ruling in *Clinton v. New York*, 524 U.S. 417 (1998), which held that Congress may not create a statutory provision permitting the executive to cancel certain portions of the statute. *Id.* at 445. As Judge Plager noted in his dissent in this case, the Supreme Court "recently . . . has made clear that the Presentment Clause requires that any modification to a statute must follow" the enactment and presentment procedures set forth in

Article I. *See Terran v. Secretary of HHS*, 195 F.3d 1302, 1319 (Fed. Cir. 1999) (Flager, J., dissenting).

Second, Plaintiff's petition would seek clarification of the fundamental confusion surrounding the standard of proof for claims brought under the Vaccine Act, which is designed to make compensation available to vaccine-injured persons "quickly, easily, and with certainty and generosity." *Bunting v. Secretary of HHS*, 931 F.2d 867, 869 (Fed. Cir. 1991) (citation omitted). The question at issue is whether the standard for consideration of expert testimony in Vaccine Act cases is governed by the Vaccine Act itself or is open to broad judicial discretion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). This is a systemic question of central importance to all cases under the Vaccine Act, but the courts have provided little guidance in this area, and clarification is needed if the purposes of the Act are to be effectuated. Moreover, this question is appropriate for consideration by the Supreme Court in the absence of any conflict among the federal courts because cases under the Act arise only via one judicial route, decision by a Special Master in the Court of Federal Claims, review by that court and appeal to the Federal Circuit.

Thus, Plaintiff's petition for certiorari, which will present issues at the heart of the separation of powers, expose a clear contradiction between decisions of this Court and the Supreme Court, and seek clarification of an important issue of federal statutory construction, clearly will raise "substantial questions" justifying stay of this court's mandate.

Indeed, the petition will raise the kind of issues classically seen as worthy of certiorari, and so has a significant likelihood of being granted and of resulting in eventual reversal of the judgment below. *See* SUP. CT. R. 10(c) (among the reasons for a grant of certiorari are that an appellate court "has decided an important federal question in a way that conflicts with relevant decisions of this Court," or that an appellate court has "decided an important question of federal law that has not been, but should be, settled by this Court"). The conflict between the panel's ruling and the Supreme Court's decision in *Clinton*, and the serious questions concerning the appropriate standard for decision of claims under the Vaccine Act, which has not yet been addressed by the Supreme Court, provided two distinct grounds on which certiorari might be granted. Furthermore, in light of the similarities between section 300aa-14(a) and the statute struck down in *Clinton v. New York*, "there is little question that [the Act] violates the Presentment Clause of the Constitution." *See Terran*, 195 F.3d at 1321 (Plager, J., dissenting). There is, therefore, at least a significant probability that Plaintiff will prevail on the merits in the Supreme Court if certiorari is granted.

Conclusion

For the foregoing reasons, this Court should recall and stay its mandate for ninety days pending Plaintiff's petition for a writ of certiorari to the United States Supreme Court. Further, in light of the time-sensitive

nature of this matter, Plaintiff requests that the Court rule on this motion expeditiously.

Respectfully submitted,

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Counsel for Petitioner/Appellant

February 29, 2000

CERTIFICATE OF SERVICE

On the 29th day of February, 2000, I, Rachel L. Brand, certify that I caused to be served by first class U.S. Mail, postage pre-paid, a copy of Appellant's Motion for Recall and Stay of the Mandate Pending the Filing of a Petition for Writ of Certiorari upon the following:

Vincent J. Matanoski, Esq.
Department of Justice
P.O. Box 146
Benjamin Franklin Station
Washington, D.C. 20044-0146

/s/ Rachel L. Brand
Rachel L. Brand

42 U.S.C. § 300aa-1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1986 Act. Senate Report No. 99-380, Related Reports, and Statement by President, see 1986 U.S.Code Cong. and Adm. News, p. 6287.

Effective Dates

1986 Act. Section 323 of Pub.L. 99-660, as amended by Pub.L. 100-203, Title IV, § 4302(a), Dec. 22, 1987, 101 Stat. 1330-221, provided that:

"**(a) General rule.** – Part 1 of title XXI of the Public Health Service Act [part 1 of this subchapter] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and parts A and B of subtitle 2 of such title [subparts A and B of part 2 of this subchapter] shall take effect on October 1, 1988 and parts C and D of such title [subparts C and D of part 2 of this subchapter] and this title [see Short Title note under section 201 of this title] shall take effect on the date of the enactment of the Vaccine Compensation Amendments of 1987 [Dec. 22, 1987].

"**(b) Insufficiency of funds.** – If at any time there are insufficient funds to pay all of the claims payable under subtitle 2 of title XXI of the Public Health Service Act [part 2 of this subchapter] for 180 days, such subtitle shall cease to be in effect until sufficient funds to pay all of the claims under such subtitle become available."

Separability of Provisions

Section 322 of Pub.L. 99-660, as amended by Pub.L. 101-239, Title VI, § 6602, Dec. 19, 1989, 103 Stat. 2293; Pub.L. 101-502, § 5(g)(1), Nov. 3, 1990, 104 Stat. 1288, provided that:

"**In general.** – Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [subparts A and B of part 2 of this subchapter], as added by section 311(a) [this subchapter], or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"**(b) Special rule.** – If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 to title XXI of the Public Health Service Act [section 6601 of Pub.L. 101-239, amending sections 300aa-10, 300aa-11, 300aa-12, 300aa-13, 300aa-14, 300aa-15, 300aa-16, 300aa-17, 300aa-21, 300aa-23, 300aa-26, and 300aa-27 of this title] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

[Amendment by section 5(g)(1) of Pub.L. 101-502 to section 322(a) of Pub.L. 99-660 effective Nov. 14, 1986, see section 5(h) of Pub.L. 101-502, set out as a note under section 300aa-11 of this title.]

Prior Provisions

A prior section 300aa-1, Act July 1, 1944, § 2102, was renumbered section 2302 by Pub.L. 99-660 and transferred to section 300cc-1 of this title, renumbered section 2502 by Pub.L. 100-607 and transferred to section 300aaa-1 of this title, renumbered section 2602 by Pub.L. 100-690, and renumbered section 2702 by Pub.L. 101-381.

A prior section 2101 of Act July 1, 1944, was renumbered section 2301 by Pub.L. 99-660 and classified to section 300cc of this title, renumbered section 2501 by Pub.L. 100-607 and classified to section 300aaa of this title, renumbered section 2601 by Pub.L. 100-690, and renumbered section 2701 by Pub.L. 101-381.

Evaluation of Program; Study and Report to Congress

Pub.L. 101-239, Title VI, § 6601(t) Dec. 19, 1989, 103 Stat. 2293, provided that: "The Secretary of Health and Human Services shall evaluate the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [this subchapter] and shall report the results of such study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than January 1, 1992."

Related Studies

Section 312 of Pub.L. 99-660 provided that:

"**(a) Review of pertussis vaccines and related illnesses and conditions.** – Not later than 3 years after the effective date of this title [see section 323 of Pub.L. 99-660 set out as a note under this section], the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (c)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

"**(1)** Hemolytic anemia.

"**(2)** Hypsarrhythmia.

"**(3)** Infantile spasms.

"**(4)** Reye's syndrome.

"**(5)** Peripheral mononeuropathy.

"**(6)** Deaths classified as sudden infant death syndrome.

"**(7)** Aseptic meningitis.

"**(8)** Juvenile diabetes.

"**(9)** Autism.

"**(10)** Learning disabilities.

"**(11)** Hyperactivity.

"**(12)** Such other illnesses and conditions as the Secretary may choose to review or as the Advisory Commission on Childhood Vaccines

established under section 2119 of the Public Health Service Act [section 300aa-19 of this title] recommends for inclusion in such review.

The review under this subsection shall include notice and opportunity for a public hearing, consideration of written information submitted by the public, and consultation with such Advisory Commission.

"**(b) Findings with respect to pertussis.** – Not later than 3 years after the effective date of this title, the Secretary shall make, and publish in the Federal Register, the following specific findings:

"**(1)** Whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated, by pertussis-containing vaccines.

"**(2)** For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), the circumstances under which such causation or aggravation can reasonably be determined to occur.

"**(3)** For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), and for each illness or condition set forth in the Vaccine Injury Table under section 2114 of the Public Health Service Act [section 300aa-14 of this title] the time periods within which the first symptom or manifestation of onset or aggravation of each such illness or condition can reasonably be determined to occur after pertussis vaccination.

"**(c) Revision of table with respect to pertussis vaccines.** – At the same time the Secretary publishes in the Federal Register findings under subsection (b), the Secretary shall propose regulations to amend the Vaccine Injury Table under section 2114 of the Public Health Service Act [section 300aa-14 of this title] as a result of such findings. Not later than 42 months after the effective date of this title, the Secretary shall promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

"**(d) Review of MMR vaccines and related illnesses and conditions.** – Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review similar to the review conducted under subsection (a) with respect to the potential relationship between vaccines containing rubella (including MMR) and radiculoneuritis. The review under this subsection shall include notice and opportunity for a public hearing, consultation with the Advisory Commission on Childhood Vaccines and consideration of written information submitted by the public. Not later than 3 years after the effective date of this title, the Secretary shall make and publish in the Federal Register findings similar to those required by subsection (b) and shall, if appropriate, propose similar regulations (and thereafter promulgate such regulations) to those required by subsection (c), which respect to compensation under the National Vaccine Injury Compensation Program established under section 2110 of the Public Health Service Act [section 300aa-10 of this title] for radiculoneuritis caused, contributed to, or significantly aggravated by vaccines containing rubella.

"**(e) Pertussis and MMR studies.** –

"**(1)** In order to assist the Secretary in making the findings required under subsections (b) and (d), the Secretary shall, in accordance with subparagraph (B), arrange for the conduct of studies of –

"**(A)** the relationship between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the illnesses or conditions set forth in paragraphs (1) through (11) of subsection (a),

"**(B)** the relationship between vaccines containing pertussis and any other illnesses and conditions, as selected by the Secretary or the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title], and

"**(C)** the relationship between vaccines containing rubella (including MMR) and radiculoneuritis.

"**(2)(A)** The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the studies required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

"**(B)** If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct

such study and prepare and submit the reports thereon as provided in paragraph (3).

"(C) The Institute of Medicine or other group or association conducting the studies required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title].

"(3) Reports on the results of the studies required by paragraph (1) shall be completed and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the State and to the Secretary not later than 32 months after the effective date of this title. Upon submission to the Secretary, the reports shall be made available to the public.

"(4) There are authorized to be appropriated such sums as are necessary for the purpose of making payments for the conduct of the studies required under this subsection.

"(f) **Definitions.** – For purposes of this section:

"(1) The term 'medical and scientific information' includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official Government publications, as well as relevant unpublished information, data, studies, and observations.

"(2) The term 'MMR' means a vaccine containing material intended to prevent or confer

immunity against measles, mumps, and rubella disease."

Review of Warnings, Use Instructions and Precautionary Information

Section 314 of Pub.L. 99-660 provided that: "Not later than 1 year after the effective date of this title [see section 323 of Pub.L. 99-660, set out as a note under this section] and after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title] and with other appropriate entities, the Secretary of Health and Human Services shall review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 2114 of the Public Health Service Act [section 300aa-14 of this title] and shall by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines. If the Secretary determines that any such warning, instruction, or information is inadequate for such purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title."

Study of Other Vaccine Risks

Section 313 of Pub.L. 99-660 provided that:

"**(a) Study.** –

"**(1)** Not later than 3 years after the effective date of this title [see section 323 of Pub.L. 99-660, set out as a note under this section] the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title] –

"**(A)** arrange for a broad study of the risks (other than the risks considered under section 102) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act [section 300aa-14 of this title] and

"**(B)** establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include –

"**(i)** the circumstances under which any such vaccine should not be administered,

"**(ii)** the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

"**(iii)** the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher

risk of major adverse reactions to such vaccine than the general population of potential recipients.

"**(2)(A)** The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

"**(B)** If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

"**(C)** The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title].

"**(b) Revision of guidelines.** – The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

"**(c) Factors affecting guidelines.** – Guidelines under subsection (a) shall take into account –

"**(1)** the risk to potential recipients of the vaccines with respect to which the guidelines are established,

"**(2)** the medical and other characteristics of such potential recipients, and

"**(3)** the risks to the public of not having such vaccines administered.

"**(d) Dissemination.** – The Secretary shall widely disseminate the guidelines established under subsection (a) to –

"**(1)** physicians and other health care providers,

"**(2)** professional health associations,

"**(3)** State and local government and agencies, and

"**(4)** other relevant entities."

Waiver of Paperwork Reduction

Section 321 of Pub.L. 99-660 provided that: "Chapter 35 of title 44, United States Code [44 U.S.C.A. § 3501 et seq.] shall not apply to information required for purposes of carrying out this title [Title III of Pub.L. 99-660, see Short Title of 1986 Amendment note set out under section 201 of this title] and implementing the amendments made by this title."

Subpart A – Program Requirements

§ 300aa-10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

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§ 300aa-11. Petitioners for compensation

(a) General Rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal

Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and –

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title, be considered the date the petition was filed if the petition was filed

within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart.

(4) If in a civil action brought against a vaccine administrator or manufacturer before the effective date of this subpart, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(5)(A) A plaintiff who on the effective date of this subpart, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this subpart or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before

November 15, 1988, such person may not file a petition under subsection (b) of this section for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

(8) If on the effective date of this subpart there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1) of this section, file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this subpart if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain –

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died –

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table –

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time

period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine or (ii) died from the administration of the vaccine, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

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§ 300aa-12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation

under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa-11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information –

(A) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters

which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master.

The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts[1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrates shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of

Federal Claims on the number of petitions filed under section 300aa-11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa-11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall –

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record

without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall –

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e) of this section.

(B) In conducting a proceeding on a petition a special master –

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information –

(I) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before the effective date of this part, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information –

> (i) which is trade secret or commercial or financial information which is privileged and confidential, or
>
> (ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a

review of the record of the proceedings and may thereafter –

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall

be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's[1] judgment with such court of appeals.

(g) Notice

If –

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section) after the date on which the petition was filed,

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[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of this title or the petitioner may choose under section 300aa-21(b) of this title to have the petition remain before the special master or court, as the case may be.

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§ 300aa-13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole –

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(b) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine" –

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record –

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the courts of the injury,

disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa-11 of this title.

§ 300aa-14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I. DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).

Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis).....	3 days
C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days

D.	Residual seizure disorder in accordance with subsection (b)(2).....	3 days
E.	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A.	Anaphylaxis or anaphylactic shock	24 hours
B.	Encephalopathy (or encephalitis).....	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C.	Residual seizure disorder in accordance with subsection (b)(2).....	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).

D.	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
A.	Paralytic polio	
	– in a non-immunodeficient recipient.....	30 days
	– in an immunodeficient recipient.....	6 months
	– in a vaccine-associated community case.....	Not applicable
B.	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable
IV.	Inactivated Polio Vaccine.	
A.	Anaphylaxis or anaphylactic shock	24 hours

B.	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a) of this section:

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete, hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if –

(A) in the case of a measles, mumps, or rubella vaccine or any combination of

such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented

by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa-11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d) of this section, such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine

Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following –

> **(A)** receipt of any recommendation of the Commission, or
>
> **(B)** 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) of this section or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) of this section to include –

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) of this section to include –

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

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§ 300aa-15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which –

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa-16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which –

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate

taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subpart may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section and may also include an amount, not to exceed a combined total of $30,000, for –

(1) lost earnings (as provided in paragraph (3) of subsection (a) of this section),

(2) pain and suffering (as provided in paragraph (4) of subsection (a) of this section), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e) of this section.[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) of this section shall be sufficient to enable the compensated person to remain living at home.

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[1] So in original. Probably should be preceded by a closing parenthesis.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a) of this section, compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover –

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before the effective date of this subpart, filed a civil action for damages for any vaccine-

related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa-11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this subpart in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa-11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa-21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) of this section shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa-12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa-21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C.A. § 901 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subpart the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) of this section in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) of this section are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa-21(a) of this title shall not apply to a civil

action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and –

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subpart shall be made by the Secretary from appropriations under subsection (j) of this section.

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this subpart shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of Title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subpart there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B) of this section. Amounts appropriated under this subsection shall remain available until expended.

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§ 300aa-16. Limitations of actions

(a) General rule

In the case of –

(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this subpart, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after the effective date of this subpart, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than

36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this subpart, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this subpart, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa-11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect

to a vaccine-related injury or death covered under the revision of the table if –

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa-11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa-21(a) of this title to file the civil action or (2) an election is made under section 300aa-21(b) of this title to withdraw the petition.

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§ 300aa-19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a

term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall –

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa-27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa-25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

Subpart B – Additional Remedies

§ 300aa-21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-1200 of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the clerk of the United States Court of Federal Claims –

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator

or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after the effective date of this part, see section 300aa-11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa-11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if –

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa-12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title, or

(2) the court fails to enter a judgment under section 300aa-12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa-12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa-11 of this title shall, except as provided in section 300aa-16(b) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, c. 373, Title XXI, § 2121, as added Nov. 14, 1986, Pub.L. 99-660, Title III, § 311(a), 100 Stat. 3772, and amended Dec. 22, 1987, Pub.L. 100-203, Title IV, §§ 4304(c), 4307(8), 101 Stat. 1330-224, 1330-225, Pub.L.100-203, Title IV, § 4308(c), as added July 1, 1988, Pub.L. 100-360, Title IV, § 411(o)(3)(A), 102 Stat. 808; Dec. 19, 1989, Pub.L. 101-289, Title VI, § 6601(n), 103 Stat. 2291; Nov. 8, 1990, Pub.L. 101-502, § 5(f), 104 Stat. 1288; Nov. 26, 1991, Pub.L. 102-168, Title II, § 201(d)(3), 105 Stat. 1103; Oct. 29, 1992, Pub.L. 102-572, Title IX, § 902(b)(1), 106 Stat. 4516.)

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§ 300aa-22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows –

> **(A)** that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or
>
> **(B)** by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and

section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

§ 300aa-23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with

respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in –

> **(A)** fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,
>
> **(B)** intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or
>
> **(C)** other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

Subpart C – Assuring Safer Childhood Vaccination Program in United States

§ 300aa-25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine –

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary –

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa-14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this subpart. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this subpart.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except –

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

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§ 300aa-26. Vaccine information

(a) General rule

Not later than 1 year after the effective date of this subpart, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised –

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include –

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

(5) to (10) repealed. Pub.L. 103-183, Title 7, § 708(b)(2), Dec. 14, 1993, 107 Stat. 2242

(d) Health care provider duties

On and after a date determined by the Secretary which is –

> **(1)** after the Secretary develops the information materials required by subsection (a) of this section, and
>
> **(2)** not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a) of this section, supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

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§ 300aa-27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall –

> (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the

market on the effective date of this subpart and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section.

(c) Report

Within 2 years after the effective date of this subpart, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on

Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

---

§ 300aa-32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

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42 C.F.R.

SUBCHAPTER I – (RESERVED)
SUBCHAPTER J – VACCINES

PART 100 – VACCINE INJURY COMPENSATION

Sec.

100.1 Applicability.

100.2 Average cost of a health insurance policy.

100.3 Vaccine injury table.

AUTHORITY: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act. 100 Stat. 3767, as amended (42 U.S.C. 300aa-15); § 100.3, the Vaccine Injury Table, issued under sec. 312 of Pub. L. 99-660. 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and sec. 2114(c) of the PHS Act (42 U.S.C. 300aa-14(c)).

§ 100.1 Applicability.

This part applies to the National Vaccine Injury Compensation Program (VICP) under subtitle 2 of title XXI of the Public Health Service (PHS) Act.

[60 FR 7693, Feb. 8, 1995]

§ 100.2 Average cost of a health insurance policy.

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS Act, 42 U.S.C. 300aa.15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting

lost earnings, less certain deductions. One of the deductions is the average cost of a health insurance policy, as determined by the Secretary of Health and Human Services. The Secretary has determined that the average cost of a health insurance policy is $158.00 per month. This amount will be revised to reflect the changes in the medical care component of the Consumer Price Index (All Urban Consumers, U.S. City Average), published by the United States Bureau of Labor Statistics, plus 2 percent per year. The revised amounts will be effective upon their delivery by the Secretary to the United States Claims Court, and the amounts will be published in a notice in the Federal Register from time to time as determined by the Secretary.

[57 FR 28099, June 24, 1992, as amended at 60 FR 7693, Feb. 8, 1995]

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. DTP; P; DT; Td; or Tetanus Toxoid; or in any combination with Polio; or any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Pertussis Bacteria, or Specific Pertussis Antigen(s):	
A. Anaphylaxis or anaphylacic shock	4 hours.
B. Encephalopathy (or encephalitis)	72 hours.
C. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
II. (a). Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component:	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
C. Residual seizure disorder in accordance with subsection (b)(3)	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
D. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

VACCINE INJURY TABLE

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
II. (b). In the case of measles, mumps, rubella (MMR), measles, rubella (MR) or rubella vaccines only:	
A. Chronic Arthritis	42 days.
B. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Polio Vaccine (other than inactivated Polio Vaccine):	
A. Paralytic Polio	
In a non-immunodeficient recipient	30 days.
In an immunodeficient recipient	6 months.
In a vaccine associated community case	Not applicable.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Inactivated Polio Vaccine:	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

(b) Qualifications and aids to interpretation. The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

(1) Anaphylaxis and anaphylactic shock. For purposes of paragraph (a) of this section: Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) Encephalopathy. For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

* * *

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

MICHELE Y. TERRAN, as legal representative of JULIE F. TERRAN, a minor, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	No.: Special Master Assigned: None

PETITION FOR VACCINE COMPENSATION

NOW COMES your Petitioner, MICHELE Y. TERRAN, as the legal representative of JULIE F. TERRAN, a minor, and in accordance with 42 U.S.C. Sections 300 aa-10, *et. seq.*, files this Petition For Vaccine Compensation and states as follows:

1. The Petitioner, MICHELE Y. TERRAN, is the legal representative of JULIE F. TERRAN, a minor born February 10, 1992 and is, in fact, the natural mother of said minor;

2. That Petitioner, MICHELE Y. TERRAN, has caused to be attached to this Petition as Exhibit "A" her Affidavit which states, in summary, as follows:

a) That on the afternoon of August 10, 1992, JULIE F. TERRAN, petitioner's daughter, born February

10, 1992, received vaccines set forth in the Vaccine Injury Table, to wit, Diphtheria, Fertussis and Tetanus Vaccine (hereinafter "D.P.T.") and Oral Polio Vaccine (hereinafter "O.P.V.");

b) That said vaccines were administered to JULIE F. TERRAN at the offices of Gary Berebitsky, M.D. located in Phoenix, Arizona;

c) That at approximately 6:00 A.M. the morning of August 11, 1992, upon awakening, JULIE F. TERRAN suffered an episode lasting approximately seven (7) seconds wherein one of her arms became stiff, an episode which, in retrospect, petitioner now believes was a seizure, without fever;

d) That on August 12, 1992, JULIE F. TERRAN, while in the custody of her babysitter, at the approximate hour of 4:45 P.M., did suffer an episode reported to be a seizure, without fever, an episode responded to by paramedics (Reference Incident Report 92086148 contemporaneously filed herein);

e) That on August 12, 1992, JULIE F. TERRAN, at the approximate hour of 6:30 P.M. did, in petitioner's presence, suffer what petitioner has come to recognize as a seizure, a seizure lasting approximately one (1) minute which was without fever, an episode responded to, again, by paramedics (Reference Incident Report 92086180 contemporaneously filed herein);

f) That JULIE F. TERRAN was then transported to the emergency room at Phoenix Children's Hospital on August 12, 1992 and admitted as an in-patient in said facility, again with no fever;

g) That on August 13, 1992, while an in-patient at Phoenix Children's Hospital, JULIE F. TERRAN did suffer, in the presence of hospital personnel, what they describe as a seven (7) minute generalized seizure, again, without temperature;

h) That for the one (1) year period immediately following August 13, 1992, and thereafter, JULIE F. TERRAN has suffered from multiple, additional seizures including, without limitation, a generalized seizure, despite being on phenobarbital medication at the time, lasting approximately fifty (50) minutes on September 2, 1992;

i) That petitioner is informed and believes that within fifteen (15) hours of the aforesaid administration of D.P.T. vaccine, and as a direct and proximate result of the aforesaid administration of said D.P.T. vaccine, said minor, JULIE F. TERRAN, sustained an injury, to wit, encephalopathy, a residual seizure disorder, a shock collapse and a hyporesponsive/hypotensive event, with proximately resulting mental and physical disability;

j) That petitioner is informed and believes that JULIE F. TERRAN, a minor, has suffered the residual effects or complications of such injury for more than six (6) months after the administration of the subject D.P.T. vaccine and has incurred and will incur in the future unreimburseable expenses due in whole or in part to such injury in an amount greater than $1,000.00

k) That no one has previously collected an award or settlement of a civil action for damages for the vaccine-related injury of JULIE F. TERRAN nor has any such civil litigation ever been filed.

3. Other available relevant records are submitted contemporaneously herewith in a separate volume entitled "Evidentiary Notebook: Volume I". The aforesaid notebook contains the following categories of medical records and reports:

Exhibit

1. Newborn Records,
   Good Samaritan Regional Medical Center
   a) APGAR scores, 8, 9
2. Good Samaritan Regional Medical Center, Pediatric Records, Pre and Post-Immunization
   a) Immunization Record
   b) Pediatrician's Handwritten Office Chart
   c) Airevac Report, 09/02/92
   d) M.R.I. Head Scan Reports, Multiple
3. St. Joseph's Hospital and Medical Center
   a) E.E.G. Report, 12/22/93
4. Phoenix Children's Hospital
   a) Emergency Room Visit of 08/12/92 and Follow-Up Hospitalization
   b) Hospitalization, 09/02/92
   c) Reports of Allen M. Kaplan, M.D., Director, Department of Pediatric Neurology
   d) E.E.G. Reports
      1) 08/13/92
      2) 09/02/92
      3) 02/25/93
      4) 05/21/93
      5) 11/23/93
5. Maryvale Samaritan Medical Center
   a) Emergency Room Visit, 09/02/92 (prior to transfer to Phoenix Children's Hospital)
   b) Balance of Records

6. Rehability Center
   a) Occupational Therapy Screening
   b) Speech and Language Assessment
   c) Physical Therapy Screening

7. Health Psychology Associates

8. Valley Radiologists Ltd.

9. Thomas F. Moore, M.D., F.A.C.S.

10. Paramedics Reports

11. Genetic Screen, Karyotype With Banding

12. Pre-Natal Care Records
    a) Paula Nadell, M.D.
    b) Charles A. Alfano, M.D.

4. That appropriate assessments, evaluations, and prognoses and other such records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, JULIE F. TERRAN, a minor, are not yet available except as the same may be contained in the Evidentiary Notebook filed herewith. An appropriate report of an expert in the field of developmental rehabilitation is in the process of being requested and the same will be forwarded as a supplement to this Petition pursuant to scheduling established by the Special Master assigned herein; Further, an appropriate report of an expert in the field of economics as to the projected cost of the care, treatment, therapy and all items claimed as damages herein is not yet available but the same will be submitted as a supplement to this Petition pursuant to scheduling established by the Special Master assigned herein.

5. That MICHELE Y. TERRAN, as Petitioner and legal representative herein, claims the following items of special damages which resulted from the aforesaid vaccine-related injury and which will be incurred by or on behalf of JULIE F. TERRAN, a minor;

a) Actual unreimbursable expenses from the date of judgment which will be for diagnosis and medical or other reasonably necessary remedial care or for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses and facilities determined to be reasonably necessary;

b) Compensation for loss of earnings after age eighteen (18);

c) Compensation for actual and projected pain and suffering and emotional distress;

d) Reasonable attorney's fees and costs incurred in proceedings on this Petition; and

e) All other damages permitted by 42 U.S.C., Section 300aa-15 (a) and all other applicable laws.

6. Minor petitioner, JULIE F. TERRAN, suffered injuries described on the Vaccine Injury Table within the time requirements of the Table from a vaccine on the Table which she received within the United States after October 1, 1988; Further, petitioner affirmatively asserts that the relevant Vaccine Injury Table herein, including the Qualification and aids to interpretation pertinent thereto, is that which existed prior to March 10, 1995.

That Petitioner, MICHELE Y. TERRAN, respectively demands compensation pursuant to 42 U.S.C., Section 300aa-15, petitioner defers a specific demand for compensation pursuant to 42 U.S.C., Section 300aa-11(e).

WHEREFORE, Petitioner, MICHELE Y. TERRAN, as legal representative and on behalf of JULIE F. TERRAN, a minor, demands judgment against Respondent, Secretary of the Department of Health and Human Services, in a sum of money adequate to compensate her as aforestated and for such other relief as this Court deems just and equitable.

DATED: July 11, 1995

Respectfully submitted,

/s/ Andrew W. Dodd
ANDREW W. DODD,
ESQUIRE
Counsel For Petitioner
21515 Hawthorne Boulevard
Suite 840
Torrance, CA 90503
(310) 316-6223

EXHIBIT "A"

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

MICHELE Y. TERRAN, as legal representative of JULIE F. TERRAN, a minor, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	NO: -V

AFFIDAVIT

STATE OF ARIZONA)
) SS.
COUNTY OF MARICOPA)

MICHELE Y. TERRAN, being first and duly sworn to oath, deposes and states as follows:

1. That she is the petitioner herein, to wit, the mother of JULIE F. TERRAN, a minor;

2. That she is familiar with the facts and circumstances surrounding the immunization of JULIE F. TERRAN, a minor and her daughter, and makes this affidavit upon her own knowledge except as to those matters stated on information and belief and, as to those matters, she believes the same to be true;

3. That on the afternoon of August 10, 1992, JULIE F. TERRAN, your affiant's daughter, born February 10, 1992, received vaccines set forth in the Vaccine Injury Table, to wit, Diphtheria, Pertussis and Tetanus Vaccine (hereinafter "D.P.T.") and Oral Polio Vaccine (hereinafter "O.P.V.");

4. That said vaccines were administered to JULIE F. TERRAN at the offices of Gary Berebitsky, M.D. located in Phoenix, Arizona;

5. That at approximately 6:00 A.M. the morning of August 11, 1992, upon awakening, JULIE F. TERRAN suffered an episode lasting approximately seven (7) seconds wherein one of her arms became stiff, an episode which, in retrospect, your affiant now believes was a seizure, without fever;

6. That on August 12, 1992, JULIE F. TERRAN, while in the custody of her babysitter, at the approximate hour of 4:45 P.M., did suffer an episode reported to be a seizure, without fever, an episode responded to by paramedics (Reference Incident Report 92086148 contemporaneously filed herein);

7. That on August 12, 1992, JULIE F. TERRAN, at the approximate hour of 6:30 P.M. did, in your affiant's presence, suffer what your affiant has come to recognize as a seizure, a seizure lasting approximately one (1) minute which was without fever, an episode responded to, again, by paramedics (Reference Incident Report 92086180 contemporaneously filed herein);

8. That JULIE F. TERRAN was then transported to the emergency room at Phoenix Children's Hospital on

August 12, 1992 and admitted as an in-patient in said facility, again with no fever;

9. That on August 13, 1992, while an in-patient at Phoenix Children's Hospital, JULIE F. TERRAN did suffer, in the presence of hospital personnel, what they describe as a seven (7) minute generalized seizure, again, without temperature;

10. That for the one (1) year period immediately following August 13, 1992, and thereafter, JULIE F. TERRAN has suffered from multiple, additional seizures including, without limitation, a generalized seizure, despite being on phenobarbital medication at the time, lasting approximately fifty (50) minutes on September 2, 1992;

11. That your affiant is informed and believes that within fifteen (15) hours of the aforesaid administration of D.P.T. vaccine, and as a direct and proximate result of the aforesaid administration of said D.P.T. vaccine, said minor, JULIE F. TERRAN, sustained an injury, to wit, encephalopathy, a residual seizure disorder, a shock collapse and a hyporesponsive/hypotensive event, with proximately resulting mental and physical disability;

12. That affiant is informed and believes that JULIE F. TERRAN, a minor, has suffered the residual effects or complications of such injury for more than six (6) months after the administration of the subject D.P.T. vaccine and has incurred and will incur in the future unreimburseable expenses due in whole or in part to such injury in an amount greater than $1,000.00;

13. That no one has previously collected an award or settlement of a civil action for damages for the vaccine-related injury of JULIE F. TERRAN nor has any such civil litigation ever been filed.

Further affiant sayeth not.

/s/ Michele Y. Terran
MICHELE Y. TERRAN,
Affiant

SUBSCRIBED AND SWORN to before me this 6 day of July, 1995

/s/ Illegible
NOTARY PUBLIC
My Commission Expires
My Commission Expires Jan. 30, 1996

Supreme Court, U.S.
FILED
AUG 2 2000

Nos. 99-1747 and 99-1749

In the Supreme Court of the United States

FRANK O'CONNELL AND LISA O'CONNELL, LEGAL REPRESENTATIVES OF THEIR DAUGHTER, KELLI-ANN O'CONNELL, PETITIONERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES

MICHELE Y. TERRAN, AS LEGAL REPRESENTATIVE OF JULIE F. TERRAN, A MINOR, PETITIONER

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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26pp

QUESTIONS PRESENTED

1. Whether 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998), a provision of the National Childhood Vaccine Injury Act of 1986 that allows the Secretary of Health and Human Services to promulgate regulations embodying modifications to an initial Vaccine Injury Table set out in the Act, violates the Presentment Clause of the Constitution Art. I, § 7, Cl. 2, or represents an unconstitutional delegation of legislative power.

2. In No. 99-1749, whether the United States Court of Appeals for the Federal Circuit applies a permissible standard for proof of causation in compensation proceedings under the Act.

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In the Supreme Court of the United States

No. 99-1747

FRANK O'CONNELL AND LISA O'CONNELL,
LEGAL REPRESENTATIVES OF THEIR DAUGHTER,
KELLI-ANN O'CONNELL, PETITIONERS

v.

DONNA E. SHALALA, SECRETARY OF
HEALTH AND HUMAN SERVICES

No. 99-1749

MICHELE Y. TERRAN, AS LEGAL REPRESENTATIVE
OF JULIE F. TERRAN, A MINOR, PETITIONER

v.

DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES

ON PETITIONS FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals in No. 99-1749 (99-1749 Pet. App. 1a-40a) is reported at 195 F.3d 1302. The opinion of the Court of Federal Claims in that case (99-1749 Pet. App. 41a-58a) is reported at 41 Fed. Cl. 330, and the opinion of the Special Master (99-1749 Pet. App. 59a-92a) is unreported.

The opinion of the court of appeals in No. 99-1747 (99-1747 Pet. App. 1-5) is unreported. The opinion of the Court of Federal Claims (99-1747 Pet. App. 34-41) is reported at 40 Fed. Cl. 891. The opinion of the Special Master (99-1747 Pet. App. 7-33) is unreported.

JURISDICTION

The judgments of the court of appeals were entered on October 27, 1999 (No. 99-1749) and November 1, 1999 (No. 99-1747). Petitions for rehearing were denied on February 2, 2000 (99-1747 Pet. App. 45-46; 99-1749 Pet. App. 93a-94a). The petitions for a writ of certiorari were filed on May 1, 2000 (No. 99-1749) and May 2, 2000 (No. 99-1747). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Congress enacted the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act or the Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (codified at 42 U.S.C. 300aa-1 *et seq.* (1994 & Supp. IV 1998)), to promote national childhood immunization programs by establishing a tax-based federal compensation scheme for children injured by vaccines, thus reducing the number of traditional tort actions filed against vaccine manufacturers. See Pet. App. 5a-6a.[1] The Act first creates a National Vaccine Program, "to achieve optimal prevention of naturally occurring human infectious diseases through immunization and to achieve optimal prevention of the adverse reactions to vaccines." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. I, at 9 (1986); see 42 U.S.C. 300aa-1 to 300aa-6. It then establishes a National Vaccine Injury Compensation Program (the

[1] Unless otherwise noted, appendix citations are to the appendix to the petition in No. 99-1749.

Program), funded by a special tax on vaccines, under which "compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-15(i); see also 26 U.S.C. 9510 (1994 & Supp. IV 1998).

Claimants under the Program may establish a right to compensation in one of two ways. An injury is presumed to have been caused by a vaccine, and therefore to be compensable, if it is listed on the Program's Vaccine Injury Table (the Table) and first manifests itself within a set period of time, also prescribed by the Table, after administration of the vaccine. See 42 U.S.C., 300aa-14(a) (1994 & Supp. IV 1998); 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(A); 42 C.F.R. 100.3(a). The Table is supplemented by a set of "qualifications and aids to interpretation" providing relevant definitions and explanations. See 42 U.S.C. 300aa-14(b) (1994 & Supp. IV 1998); 42 C.F.R. 100.3(b). The presumption of causation, where it applies, may be rebutted by evidence that the injury was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300aa-13(a)(1)(B). If a claimant's injury is not presumed compensable under the Table, the claimant may nonetheless obtain compensation by demonstrating, by a preponderance of the evidence, that the vaccine in fact caused or significantly aggravated the injury. 42 U.S.C. 300aa-11(c)(1)(C)(ii), 300aa-13(a).

A claimant under the Program is never required to demonstrate that a vaccine was defective or that its manufacturer was negligent. The compensation available includes unreimbursed medical expenses, rehabilitation, special education, vocational training, residential and custodial care, special equipment, lost earnings, pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(a) and (e). A claimant who is dis-

satisfied with an award made under the Program may reject the award and litigate her claim under state tort law, subject to certain limitations. 42 U.S.C. 300aa-11(a), 300aa-21. Applicable statutes of limitations are tolled while the claimant exhausts the alternative remedy provided by the Act. 42 U.S.C. 300aa-16(c).

The Act itself establishes an "initial" Vaccine Injury Table (the Initial Table), and it authorizes the Secretary of Health and Human Services to "promulgate regulations to modify" the Table by adding or deleting injuries or changing the onset periods that trigger a presumption of compensability. See 42 U.S.C. 300aa-14(c)(1) to (3) (1994 & Supp. IV 1998). The legislative history indicates Congress's expectation that the Secretary would make appropriate changes to the Initial Table once "research on vaccine injury and vaccine safety * * * provide[d] more definitive information about the incidence of vaccine injury." H.R. Rep. No. 908, *supra*, at 18. Changes to the Table apply to petitions for compensation that are filed after the effective date of the final regulation adopting the change. 42 U.S.C. 300aa-14(c)(4) (1994 & Supp. IV 1998).

The Act establishes an Advisory Commission on Childhood Vaccines (ACCV) that includes health professionals, legal experts, interested citizens (including parents of children with vaccine-related injuries), and federal officials. See 42 U.S.C. 300aa-5, 300aa-19. The Secretary is required to provide the ACCV with a copy of proposed regulations before issuing them for notice and comment. 42 U.S.C. 300aa-14(d) (1994 & Supp. IV 1998). The ACCV may also ask the Secretary to propose regulations to amend the Table, and it reviews such requests made by others. The Secretary must publicly explain any decision not to undertake a rule-

making proceeding in response to a request. 42 U.S.C. 300aa-14(c)(2) (1994 & Supp. IV 1998).

2. Section 312 of the Act, 100 Stat. 3779-3780, directs the Secretary to "complete a review of all relevant medical and scientific information" on the relationship between certain vaccines and illnesses, to make and publish findings on specified questions, and to "propose regulations to amend the Vaccine Injury Table * * * as a result of such findings." The Secretary arranged for the Institute of Medicine (IOM), an arm of the National Academy of Sciences, to conduct the required study, and the Institute released its report in 1991. See Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* (Christopher P. Howson et al. eds., 1991) (the IOM Report).

The Secretary referred the IOM Report to the National Vaccine Advisory Committee (NVAC), a Public Health Service task force (the Task Force), and the ACCV. Based on the report's conclusion that there was no credible evidence of prolonged neurological damage from diphtheria-pertussis-tetanus (DPT) vaccines, the Task Force and the NVAC recommended that the Table be revised to delete encephalopathy, hypotonic hyporesponsive episode (HHE), and residual seizure disorders (RSD) as conditions presumptively associated with DPT vaccination. The ACCV concurred with respect to HHE and RSD, but it recommended that the Table continue to cover some forms of encephalopathy, under a more precise standard. In 1992 the Secretary issued proposed regulations adopting the ACCV approach. See *O'Connell* v. *Shalala*, 79 F.3d 170, 174-175 (1st Cir. 1996).[2] In 1995,

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[2] In 1993, the Secretary requested that the IOM review a newly published follow-up study of acute childhood neurological

the Secretary issued a final rule removing HHE and RSD from the Table, and modifying the definition of encephalopathy. See 42 C.F.R. 100.3(a) and (b)(2); 60 Fed. Reg. 7678-7696. The revised Table became effective on March 10, 1995, for all petitions filed after that date. See 42 C.F.R. 100.3(c).

Petitioners Francis and Lisa O'Connell sought judicial review of the 1995 regulation under the procedure set out in 42 U.S.C. 300aa-32. The United States Court of Appeals for the First Circuit concluded that "[t]he Secretary had authority to issue the regulations * * *, and she exercised that authority in a procedurally appropriate and substantively permissible manner." *O'Connell*, 79 F.3d at 182. In that proceeding, the O'Connell petitioners did not challenge the constitutionality of the Act.

3. *No. 99-1749 (Terran).* Petitioner Terran sought compensation under the Act on the ground that her daughter Julie first showed signs of RSD and encephalopathy on the day after her third DPT vaccination. Neither RSD nor Julie's non-acute encephalopathy gave rise to a presumption of compensability under the revised Table. Pet. App. 79a. After considering the evidence, the Special Master concluded that petitioner had not shown by a preponderance of the evidence that the DPT vaccine caused Julie's chronic encephalopathy or her afebrile seizures. *Id.* at 87a-91a. He accordingly denied compensation. *Id.* at 91a.

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illnesses. See 60 Fed. Reg. 7685 (1995). The IOM concluded that the evidence suggested a causal relation between DPT vaccines and certain nervous system dysfunctions in children who experienced acute neurologic illness shortly after vaccination. The Secretary reopened the regulatory comment period to allow comment on the new IOM report. See *O'Connell*, 79 F.3d at 175.

a. The Court of Federal Claims sustained the Special Master's decision. Pet. App. 41a-58a. The court concluded that it lacked jurisdiction to consider petitioner's constitutional argument that the Secretary could not modify the Initial Table. *Id.* at 47a-48a. It also held that petitioner's challenge to the revising regulations was untimely or foreclosed by previous litigation, *id.* at 48a-49a, and that application of the revised Table to petitioner's case was not impermissibly retroactive, *id.* at 49a-51a. On the merits, the court applied the standard of review set out in 42 U.S.C. 300aa-12(e)(2), and concluded that the Special Master's determinations with respect to causation were not arbitrary or capricious. Pet. App. 51a-58a.

b. The court of appeals affirmed. Pet. App. 1a-40a. Unlike the Court of Federal Claims, the court of appeals held (*id.* at 10a-16a) that petitioner was not barred from challenging the validity of the Secretary's 1995 regulations modifying the Initial Table, and that the court had jurisdiction over petitioner's claim that Congress could not constitutionally allow the Secretary to make those modifications.

Reviewing the history of the Vaccine Act (Pet. App. 5a-9a), the court explained (*id.* at 7a) that "Congress included the Initial Table in the * * * legislation, rather than delegating the creation of the first injury table to the Secretary, because it was concerned that the administrative process would significantly delay the implementation of the Vaccine Compensation Program." Congress gave the Secretary authority to promulgate regulations modifying the Table, however, because it "intended the Secretary to revise and update the Initial Table with more accurate information that would become available as a result of the research on

vaccine injuries mandated by the Vaccine Act" itself. *Id.* at 8a.

The court rejected petitioner's contention that such an arrangement violates the Presentment Clause of the Constitution (Art. I, § 7, Cl. 2). Pet. App. 17a-23a. Considering the matter in context, the court was "convinced that the Vaccine Act does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations as contemplated in the Act." *Id.* at 18a. The court noted that regulations promulgated by the Secretary "do[] not change in any way the original injury table," but rather promulgate a new Table that applies only prospectively. *Id.* at 19a. Analogizing that process to a routine "sunset" provision, the court reasoned that Congress had merely "itself decided to render the Initial Table ineffective upon the Secretary's action" in promulgating a replacement Table by regulation. *Id.* at 20a.

The court distinguished this case from *Clinton* v. *City of New York*, 524 U.S. 417 (1998), which invalidated the Line Item Veto Act, on three grounds. First, the line-item veto had to be exercised quickly, and was therefore "necessarily based on the same conditions contemplated by Congress" when it passed the affected legislation. Pet. App. 21a. In contrast, replacement of the Initial Table set out in the Vaccine Act itself by a later regulatory Table is "contingent on conditions that did not exist when [the Act] was passed." *Ibid.* Congress simply "anticipated that the facts underlying its legislation might change in the future," and granted the Secretary appropriate authority to establish a superseding Table, through the usual administrative process, "when more accurate information linking vaccines to injuries became available." *Ibid.*

Second, unlike the Line Item Veto Act, which "provided little constraint on the President's discretion to cancel a particular appropriation line item," the Vaccine Act sets forth "detailed procedures and substantive considerations" that "channel" the Secretary's discretion. Pet. App. 21a-22a. And third, whereas *Clinton* concluded that the President was "clearly contravening Congress's policy judgment when he canceled spending items under the Line Item Veto Act," under the Vaccine Act "the Secretary was executing congressional policy when she promulgated the 1995 Table." *Id.* at 22a.

The court of appeals also rejected petitioner's claim that the Vaccine Act effects an unconstitutional delegation of legislative power. Pet. App. 23a-25a. The court noted the existence of various "substantive guideposts and procedural requirements" (*id.* at 23a) under the Act: Revised Tables "must adhere to [the] same format" as the Initial Table; the Secretary must consult with the ACCV before proposing revised regulations; the compensation program automatically terminates if the total number of awards exceeds a specified number within a specified period; and the Act establishes a "broad program to study and reduce the risk of childhood vaccines," which "Congress clearly intended [to guide] the Secretary * * * when she decides to promulgate regulations to revise the injury table." *Id.* at 24a- 25a. Under those circumstances, the court concluded, "Congress provided ample guidance and limits on the Secretary's authority to promulgate revised vaccine injury tables," and therefore stayed within the permissible bounds of delegation. *Id.* at 25a.

Turning to the merits of petitioner's case, the court rejected the argument that the Special Master should have evaluated the claim using the Initial Table be-

cause Julie Terran's condition manifested itself before the effective date of the 1995 regulations. Pet. App. 25a-26a. The court explained that the Act's specific direction that new regulations would govern "petitions for compensation * * * filed after the[ir] effective date" was sufficient to "conclusively resolve[] the question" of applicability against petitioner. *Id.* at 26a.

Finally, the court considered and rejected petitioner's argument that the Special Master erred by "discounting the causation-in-fact testimony of [petitioner's] expert" and resolving the causation question against petitioner. Pet. App. at 26a-29a. The court held that the Master's conclusions with respect to the expert testimony were reasonable (*id.* at 26a-28a), and its "review of the record [did] not uncover[] any finding of fact or conclusion of law that [was] 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* at 29a (quoting 42 U.S.C. 300aa-12(e)(2)(B)). The court accordingly affirmed the Master's rejection of petitioner's claim.

Judge Plager dissented. Pet. App. 30a-40a. In his view, because Congress "included the initial Vaccine Injury Table in the statute itself," its further provisions "purport[ing] to empower the Secretary to modify the statutorily-created" Table were inconsistent with the Presentment Clause. *Id.* at 39a.

4. *No. 99-1747 (O'Connell).* The O'Connell petitioners sought Vaccine Act compensation on the ground that their daughter Kelli-Ann first showed signs of RSD and encephalopathy on the day after her second DPT vaccination. 99-1747 Pet. App. 8-9 & n.2. Her symptoms did not create a presumption of compensability under the revised Table. *Id.* at 8 n.2. After considering the evidence, the Special Master concluded that petitioners had not shown by a preponderance of

the evidence that the DPT vaccine caused Kelli-Ann to suffer from encephalopathy (*id.* at 26-29) or RSD (*id.* at 30-32). She accordingly denied compensation. *Id.* at 33.

The Court of Federal Claims sustained the Special Master's decision. 99-1747 Pet. App. 34-41. As in *Terran*, the court concluded that it lacked jurisdiction to consider petitioners' constitutional argument that the Secretary could not modify the Initial Table. *Id.* at 37-38, 39-41. The court rejected petitioners' argument that the Special Master had applied too high a standard of proof to their off-Table causation claim, and instead sustained the Master's judgment that petitioners had failed to demonstrate the existence of post-vaccine symptoms meeting "any generally accepted definition of acute encephalopathy." *Id.* at 38; see *id.* at 36-39.

The court of appeals affirmed for the reasons given in its opinion in *Terran*. 99-1747 Pet. App. 1-5. Judge Plager dissented, also for the reasons given in his opinion in *Terran*. *Id.* at 4-5. The court did not reach the Secretary's argument that petitioners' constitutional claim was precluded by their failure to raise it in their previous challenge to the validity of the 1995 regulations. *Id.* at 4.

ARGUMENT

1. Petitioners argue that the Vaccine Act violates the Presentment Clause by authorizing the Secretary to promulgate a revised Vaccine Injury Table that supersedes the Initial Table set out in the Act itself. 99-1747 Pet. 9-17; 99-1749 Pet. 16-21. The court of appeals correctly rejected that contention.

The Presentment Clause regulates the enactment of laws, not Executive rulemaking or other steps in the administration of enacted laws. See, *e.g.*, *INS* v. *Chadha*, 462 U.S. 919, 953 n.16 (1983). While Congress

may not confer on the Executive the power to amend or repeal laws, see *Clinton*, 524 U.S. at 438-441, bicameral passage and presentment are not required as a check on Executive rulemaking because such "administrative activity cannot reach beyond the limits of the statute that created it." *Chadha*, 462 U.S. at 953 n.16.

In this case, the Vaccine Act expressly authorizes and contemplates the issuance of revised Vaccine Injury Tables through administrative rulemaking. See 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998). The only distinction between the authority granted to the Secretary to promulgate those Tables and innumerable other statutory conferrals of regulatory authority on the Executive is that in this instance Congress set out an "Initial Table" in the Act itself, so that there would be a basis for providing compensation under the Act during the period after its passage and before the Secretary could complete the study, consultation, and public comment steps necessary to consider and adopt a revised Table. That distinction is not enough to turn an authorized rulemaking into a statutory "amendment" that would require passage by Congress and presentment to the President.

As the court of appeals recognized (Pet. App. 17a-23a), the Secretary's exercise of her statutory authority to promulgate regulations superseding the Initial Table does not amount to an amendment or partial repeal of the Vaccine Act. The 1995 regulations, which the Act makes applicable to petitions filed after their effective date (see 42 U.S.C. 300aa-14(c)(4) (1994 & Supp. IV 1998)), simply implement Congress's direction to issue regulations making appropriate adjustments to the Initial Table in light of research conducted after the enactment of the Act. See Pet. App. 19a. Congress itself provided that once such regulations were issued

they would supersede contrary provisions in the Initial Table, although only for proceedings commenced after the effective date of the new regulations. Compare *Clinton*, 524 U.S. at 446 n.40 (provision of Rules Enabling Act, 28 U.S.C. 2072(b), that "[a]ll laws in conflict with [procedural] rules [adopted by this Court] shall be of no further force or effect after such rules have taken effect" is valid because "Congress itself made the decision to repeal prior rules upon the occurrence of a particular event—here, the promulgation of procedural rules by this Court"). Such a statutory provision is constitutionally permissible, even if it in some respects "alter[s] the substantive rights" (99-1749 Pet. 17) otherwise conferred by a particular statute. See *Touby* v. *United States*, 500 U.S. 160 (1991) (upholding conferral on the Attorney General of authority to add or remove substances from the schedules of controlled substances initially prescribed by statute); *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394 (1928) (upholding provision authorizing President to raise tariffs, above amounts fixed by statute, under certain conditions); *Field* v. *Clark*, 143 U.S. 649, 680, 690-694 (1892) (upholding provision authorizing President to "suspend" the Tariff Act "for such time as he shall deem just," thereby raising tariffs, if foreign governments were imposing "reciprocally unequal and unreasonable" tariffs on specified commodities).

The court of appeals also properly distinguished the table revision provision in the Vaccine Act from the "line-item veto" provision struck down by this Court in *Clinton* v. *City of New York*. See Pet. App. 20a-22a. Unlike the Vaccine Act, the Line Item Veto Act at issue in *Clinton* did purport to give the President the power to "cancel in whole" certain types of provisions

contained in duly enacted legislation. See 524 U.S. at 436; see also *id.* at 446-447. As the court below explained, this Court's invalidation of that authority turned in large part on the Court's conclusions that the Line Item Veto Act provided few constraints on the President's discretion to cancel particular appropriation items for his own policy reasons; required the President to act within five days of the enactment of a law, so that "the President's action was necessarily based on the same conditions contemplated by Congress" in enacting the measure; and authorized exercises of "veto" authority through which the President was "clearly contravening Congress's policy judgment" concerning the canceled items. Pet. App. 21a-22a. In the present case, by contrast, "Congress set forth detailed procedures and substantive considerations in the Vaccine Act that channel [the Secretary's] discretion" to supersede the Initial Table by regulation; regulations are to be issued under Section 300aa-14(c) after study and consultation and "when more accurate information linking vaccines to injuries bec[omes] available"; and the Secretary is implementing—not contravening—congressional policy when she issues superseding regulations in conformance with the plain provisions of the Act. *Id.* at 21a; compare *Clinton*, 524 U.S. at 443-444, 445.

2. The court of appeals also correctly rejected (Pet. App. 23a-25a) petitioners' argument (97-1747 Pet. 18-25; 99-1749 Pet. 21-26) that the Vaccine Act unconstitutionally delegates legislative power to the Secretary. While Congress may not delegate its legislative power to the Executive Branch, this Court's cases reflect "a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job

absent an ability to delegate power under broad general directives." *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989). Congress may authorize the Executive to promulgate legally binding regulations, so long as it "clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Id.* at 373 (quoting *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946)).

As the court of appeals recognized, the Vaccine Act's directions to the Secretary with respect to revising the Vaccine Injury Table satisfy these requirements. As the court explained, "the Initial Table in the Act itself operates as an intelligible principle that governs subsequent, administratively created tables," because "[i]n the Initial Table, Congress identified the vaccines covered by the table, the illnesses or conditions for which compensation might be had, and the time period required for the first symptom or onset of each illness," and "revised tables must adhere to this same format." Pet App. 24a. In addition, the Act requires the Secretary to undertake further scientific study and to consult with experts and interested parties (compare *Mistretta*, 488 U.S. at 376 n.10), and then to consider, through the normal public notice-and-comment process, whether and how to modify the conditions and symptom-appearance times set out in the Initial Table. See 42 U.S.C. 330aa-1 note (Related Studies); 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998).[3] This sensible use of the

[3] In Section 312(a) and (b) of the Act, 100 Stat. 3779-3780, for example, Congress directed the Secretary to "complete a review of all relevant medical and scientific information * * * on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis" and certain specified illnesses and conditions, and to make and publish findings (through a public consultative process) concerning whether, under what

administrative process properly combines an assignment of regulatory authority to an Executive official with more-than-adequate "substantive guideposts and procedural requirements" (Pet. App. 23a) to guide and limit its exercise—limits that are enforceable through appropriate judicial review. 42 U.S.C. 300aa-32. See, *e.g.*, *Skinner* v. *Mid-America Pipeline Co.*, 490 U.S. 212, 218-219 (1989) (citing various examples of valid conferrals of broad regulatory authority on administrative agencies).[4]

Petitioners object (see 99-1749 Pet. 23-26; 99-1747 Pet. 20-21) to Congress's decision to vest the Secretary with the authority to narrow the coverage of the Initial Table, at least in the absence of new scientific evidence definitively establishing the absence of any causal connection between a vaccine and a type of injury or condition. Nothing in the Constitution or in the text or purposes of the Act, however, supports that suggested limitation on the scope of the Secretary's authority to "add to, or delete from, the [Table's] list of injuries, conditions, and deaths for which compensation may be provided or [to] change the time periods for the first

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conditions, and how quickly such vaccines could reasonably be expected to cause or significantly aggravate those illnesses or conditions. Section 312(c) of the Act then directed the Secretary, at the same time she published those findings, to "propose regulations to amend the [Initial Table] * * * as a result of such findings." *Ibid.*

[4] See also *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946) ("Private rights are protected by access to the courts to test the application of the policy in the light of these legislative declarations."); cf. *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 532-533 (1935) (distinguishing cases upholding broad legislative authorizations on the ground that the statutes considered in those cases provided notice and hearing procedures).

symptom or manifestation" of a compensable condition. 42 U.S.C. 300aa-14(c)(3) (1994 & Supp. IV 1998). To the contrary, Congress presumably conferred regulatory authority in those broad terms because it understood that adapting the Initial Table, in light of developing scientific knowledge, would require the exercise of informed administrative judgment that might either increase or decrease the scope of presumptive, Table-based compensability (always, of course, leaving claimants the opportunity to receive compensation by showing that a causal relationship is more likely than not on the facts of a particular case). Cf. *Touby*, 500 U.S. at 162 (upholding provisions authorizing the Attorney General to remove or add substances to initial statutory schedules of controlled substances); *Yakus* v. *United States*, 321 U.S. 414, 425 (1944) (authorized activities may "call for the exercise of judgment, and for the formulation of subsidiary administrative policy within the prescribed statutory framework").

3. Petitioner Terran contends (99-1749 Pet. 26-30) that this Court should grant review to resolve differences in the way different panels of the Federal Circuit have approached the question of "causation-in-fact" in Vaccine Act cases. Even if there were such an intra-circuit conflict, it would be a matter for the court of appeals itself to resolve. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957). But the cases petitioner cites do not announce materially different standards of proof. Compare *Knudsen* v. *Secretary of the Dep't of HHS*, 35 F.3d 543, 548-549 (Fed. Cir. 1994) (citing *Bunting* v. *Secretary of the Dep't of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991), and *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)) ("The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause

and effect is 'logical' and legally probable, not medically or scientifically certain," but that conclusion must be supported by a sound and reliable medical or scientific explanation.), with *Grant* v. *Secretary of the Dep't of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (requiring "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury").

The cases petitioner Terran cites do differ in that the first two, *Grant* and *Strother* v. *Secretary of the Dep't of HHS*, 21 Cl. Ct. 365 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991), involved causation in "off-Table" cases, where the petitioner is not entitled to a presumption of compensability, while the latter two, *Knudsen* and *Bunting*, were Table cases, where the petitioner is entitled to compensation unless the Secretary can show that the claimant's condition is more likely than not traceable to an identifiable cause other than the vaccine.[5] Thus, while all four cases require the same proof of causation, they properly allocate the burden of persuasion to different parties, based on whether the claimant is entitled to a Table-based presumption of compensability. In the present cases, petitioners had the burden of showing causation-in-fact to support their non-Table claims. The Special Master and the courts

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[5] In demonstrating that "factors unrelated to the administration of the vaccine" caused a child's injury, 42 U.S.C. 300aa-13(a)(1)(B), the Secretary must meet the same standard of proof that applies to a petitioner's proof of causation in "off-Table" cases. See *Knudsen*, 35 F.3d at 548. It is not enough for the Secretary to identify some other possible cause of an injury; rather, she must show, by a preponderance of the evidence, that an identifiable alternate cause "in the particular case [was] shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." *Ibid.* (quoting 42 U.S.C. 300aa-13(a)(2)).

below concluded, after reviewing the relevant evidence, that petitioners had not borne that burden. That fact-bound determination does not warrant review by this Court.

4. We note, finally, three additional factors that weigh against review in these cases.[6] First, as the Secretary argued in the court of appeals, the O'Connell petitioners' constitutional claims are barred because they could have been, but were not, raised in petitioners' previous lawsuit, brought under the statutory provision for judicial review set out in 42 U.S.C. 300aa-32, challenging the validity of the Secretary's 1995 regulations. See p. 6, *supra*; 99-1747 Pet. App. 4 (declining to reach preclusion question in light of resolution of merits issue in *Terran*); Gov't C.A. Br. 22-29 (No. 98-5134); see generally, *e.g.*, *Federated Dep't Stores, Inc.* v. *Moitie*, 452 U.S. 394, 398-399 (1981).

Second, as the Secretary also argued below, petitioner Terran did not challenge the validity of the Secretary's 1995 regulation in the manner and within the time specified by Congress in 42 U.S.C. 300aa-32. See Pet. App. 13a-16a (rejecting this argument), 48a-49a (accepting the argument, at least for non-constitutional claims); Gov't C.A. Br. 18-20 (No. 98-5161). Although the court of appeals disagreed with the Secretary's argument that the failure to bring such a challenge precluded petitioner Terran's present suit, that question would remain open should the Court

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[6] In light of these factors, and because petitioners do not rely upon (or even cite) the District of Columbia Circuit's decision in *American Trucking Associations* v. *United States Environmental Protection Agency*, 175 F.3d 1027 (1999), there is also no reason to hold the petitions in these cases pending this Court review of that decision in No. 99-1257, *Browner* v. *American Trucking Associations*, cert. granted (May 22, 2000).

grant review. See, *e.g.*, *Northwest Airlines, Inc.* v. *County of Kent*, 510 U.S. 355, 364 (1994); *Thigpen* v. *Roberts*, 468 U.S. 27, 29-30 (1984).

Third, Section 322 of the original Vaccine Act, 100 Stat. 3783, sets out a somewhat unusual "nonseverability" clause: "If any provision of this title [including provisions codified at 42 U.S.C. 300aa-1 through 300aa-34] or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid."[7] The existence of that provision underscores that petitioners' constitutional challenge to the Act's grant of regulatory authority to the Secretary also raises potentially difficult questions of remedy, severability, and redressability. Compare *Chadha*, 462 U.S. at 931-935 (addressing severability and related standing argument); *McCorkle* v. *United States*, 559 F.2d 1258, 1261 (4th Cir. 1977) (concluding that legislative veto provision was not severable and dismissing action), cert. denied, 434 U.S. 1011 (1978); cf. *Friends of the Earth, Inc.* v. *Laidlaw Envtl. Servs., Inc.*, 120 S. Ct. 693, 703-704, 706-708 (2000) (treating redressability as an aspect of Article III standing); Israel Friedman, *Inseverability Clauses in Statutes*, 64 U. Chi. L. Rev. 903 (1997). The possible need to address those issues before reaching the questions petitioners seek to present counsels against granting review in these cases.

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[7] Section 322 has been amended in ways not material to the point made here. See 42 U.S.C. 300aa-1 note (severability).

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully submitted.

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No. 99-1749

In The

Supreme Court of the United States

MICHELE Y. TERRAN, as legal representative of Julie F. Terran, a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

1. This Court has long understood that the line between what Congress must do itself and what it can delegate to an officer or agency of the Executive Branch "has not been exactly drawn," and so requires the "delicate and difficult inquiry" of the Court. *Wayman v. Southard*, 23 U.S. 1, 43, 46 (1825) (Marshall, C.J.). In *Clinton v. City of New York*, 524 U.S. 417 (1998), this Court drew such a line marking the boundary of legislative and executive power by holding the Line Item Veto Act to be a violation of the Presentment Clause. U.S. Const. art. I, § 7, cl. 2. In this case, the power of the Secretary of Health and Human Services (the "Secretary") to alter the Vaccine Injury Table (the "Table") established by the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act") crosses the line drawn in *Clinton*, and similarly, indeed more egregiously, violates the Presentment Clause.

In *Clinton*, this Court concluded that the vice of the line-item veto was that, through his "cancellation" of items in spending bills enacted by Congress, in "both legal and practical effect, the President . . . amended two Acts of Congress by repealing a portion of each," 524 U.S. at 438, but did not do so according to the procedures mandated by the Constitution, *id.* at 448. The Vaccine Act empowers the Secretary not simply to halt the operation of a statutory provision, but to affirmatively "modify" and "amend" the Table set out in the United States Code by act of Congress, as even the Court of Appeals for the Federal Circuit below conceded. Appendix to the Petition for a Writ of Certiorari ("App.") 19a. And, as in *Clinton*, the Secretary's amendment or modification of those statutory provisions was not accomplished according to the procedures required by the Constitution. Under *Clinton*, then, this power that the Vaccine Act gives to the Secretary is unconstitutional. Neither the Federal Circuit below, nor Respondent now, avoids this result by effectively distinguishing *Clinton* from the central issue here.

a. Before even mentioning *Clinton*, both the Federal Circuit and Respondent have tried to remove the Vaccine Act from Presentment Clause difficulty by claiming that the Secretary's promulgation of a Table to replace the one enacted by Congress is simply normal rulemaking and does not really amend a statute in any constitutionally significant way. This is so, they say, because the Secretary is simply "implement[ing] Congress's direction to issue regulations making appropriate adjustments to the Initial Table." Respondent's Brief in Opposition ("Opp.") at 12. *See also* App. 19a. Of course such a statement begs the question of whether those regulations unconstitutionally change a statute. Begging the question further, Respondent reminds us that, after all, Congress itself provided for these regulations to supersede its statutory Table. *See* Opp. at 12-13. That Respondent would offer such analysis, so obviously contradicting elementary principles of this Court's jurisprudence – indeed, of logic – underscores the need for this Court's attention to the issues raised by this case.

As we pointed out in our Petition for a Writ of Certiorari ("Pet."), the fact that the Secretary's action can be labeled "rulemaking" does not resolve the constitutional issue. *See* Pet. at 18. If such labels insulated the Secretary's acts from Presentment Clause scrutiny, her "rules" could effectively rewrite the U.S. Code, thereby rendering the Constitution's assignments of power a lawyer's charade. And the fact that Congress gave the Secretary this power to amend the statutory Table hardly answers the question of whether it was constitutionally permissible to do so. Congress also created the line-item veto mechanism struck down in *Clinton*. *See Clinton*, 524 U.S. at 452 (Kennedy, J., concurring) ("[O]ne Congress cannot yield up its own powers, much less those of other Congresses to follow.").

Respondent further argues that the only distinction between a garden-variety rulemaking and the Secretary's

regulatory change of the statutory Table is that Congress enacted the Table in the Vaccine Act itself. "That distinction," Respondent continues, "is not enough to turn an authorized rulemaking into a statutory 'amendment' that would require passage by Congress and presentment to the President." Opp. at 12. If this were true, then the Presentment Clause might never draw Chief Justice Marshall's line.[1]

As this Court in *Clinton* made clear, the Presentment Clause question is one of constitutional structure and procedure. *See Clinton*, 524 U.S. at 448-49 (explaining that the line-item veto of the President "is surely not a document that may 'become law' pursuant to the procedures designed by the Framers"); *id.* at 449 (Kennedy, J., concurring) ("The Constitution's structure requires a stability which transcends the convenience of the moment."). Contrary to Respondent's disparagement, the fact that an officer of the Executive Branch changes a provision of law enacted by Congress *is* central to the structural question raised by the Presentment Clause. It is possible that a Vaccine Act authorizing the Secretary to promulgate the initial Table and amend it via rulemaking would have passed muster under the Presentment Clause, as Judge Plager in dissent below suggested. *See* App. 39a. But that is not what Congress did. To accept Respondent's arguments would be to blur, if not erase, the structural line of the Presentment Clause.

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[1] If the Line Item Veto Act, instead of giving the President the power to "cancel" a spending item, had authorized the Director of the Office of Management and Budget to cancel by accelerated rulemaking a spending item enacted by Congress, would *Clinton* have been decided differently? Certainly nothing in the Court's opinion there indicates that an agency rule canceling the effect of a statutory provision would be any less offensive to the Presentment Clause than direct action by the President.

b. The Federal Circuit offered three grounds for distinguishing *Clinton* from this case, all three of which were drawn from *Clinton's* discussion of *Field v. Clark*, 143 U.S. 649 (1892). *See* App. 20a-22a. Respondent has reiterated those alleged bases for distinguishing the cases, but without explicitly relying on *Field*. *See* Opp. at 8-9, 14. Respondent's reticence is understandable, since *Field* involved an application of the nondelegation doctrine, not the Presentment Clause. *See Clinton*, 524 U.S. at 465 (Scalia, J., concurring in part and dissenting in part).

The limited assistance of these bases in resolving the Presentment Clause issue, due to the different focus of *Field*, is apparent. If the Secretary under the Vaccine Act exercises a "unilateral power to change the text of duly enacted statutes" in violation of the Presentment Clause, *Clinton*, 524 U.S. at 447, whether or not the requirements of the nondelegation doctrine are met – *i.e.*, whether the Secretary's actions were sufficiently constrained, whether that action was "based on the same conditions contemplated by Congress," and whether the action "contraven[ed] Congress's policy judgment," Opp. at 14 – is irrelevant. *See also* Pet. at 18-19 (further distinguishing *Field*). If the Secretary has *amended* the provisions of a statute, she has violated the Presentment Clause irrespective of why she did it or what guidance she followed in doing so.

Moreover, *Field* upheld an Executive Branch power far closer to the power at issue in *Clinton* – "the power to suspend an exemption from import duties," compared to "the power to cancel portions of a duly enacted statute," 524 U.S. at 443 – yet the *Clinton* Court nevertheless found that the line-item veto violated the Presentment Clause. The instant case arises from a far more extensive lawmaking power than the line-item veto, for the Secretary has promulgated as governing law her own "replacement" of Congress's statutory Table. *See* Opp. at 8. Respondent has made no effort to show how the *Field*

analysis, even if somehow shoe-horned into the Presentment Clause context, could possibly save the Secretary's Vaccine Act power under the Presentment Clause if it could not save the more modest line-item veto power in *Clinton*. Yet the Federal Circuit used the inapposite *Field* analysis to do exactly that, casting a cloud over what heretofore would have been the relatively clear scope of *Clinton*. Such trimming of a major, recent precedent of this Court surely calls for this Court's examination as a general matter, but particularly so here because, given the Federal Circuit's exclusive power to review Vaccine Act cases, that court's decision in this case will give a final imprimatur to the Secretary's expansive power to reshape this important program as she will.

2. With respect to the nondelegation argument generally,[2] Respondent simply reiterates the Federal Circuit's observation that the Vaccine Act contains "more-than-adequate 'substantive guideposts and procedural requirements' " to create an "intelligible principle" that governs the Secretary's creation of a replacement for the Congress's statutory Table. Opp. at 16 (quoting App. 23a). But, although the Vaccine Act does set out *procedures* for

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[2] Petitioner agrees with Respondent, *see* Opp. at 19 n.6, that there is no reason to defer review of this case pending the Court's decision in *Browner v. American Trucking Ass'ns*, 175 F.3d 1027 (D.C. Cir. 1999), *cert. granted*, 120 S. Ct. 2003 (May 22, 2000) (No. 99-1257). The District of Columbia Circuit's decision in that case addresses no Presentment Clause questions, and involves only a fairly unusual nondelegation issue in which the unconstitutional delegation of power might be remedied by "an interpretation without the constitutional weakness." 175 F.3d at 1038. As a result, the Court of Appeals remanded the case to the agency to permit it to make an interpretation not inconsistent with the nondelegation doctrine. The instant case, in contrast, involves not only an important Presentment Clause issue, but also a nondelegation claim that cannot be avoided by a limiting interpretation of the statute.

the Secretary to follow, Respondent has not shown how those procedures constitute "*substantive* guideposts." Pet. at 21-22 (emphasis added).

More specifically, the essential nondelegation problem in this case is the lack of congressional guidance as to how the Secretary should act when scientific knowledge neither confirms nor denies that a particular vaccine can cause a particular injury. *See* Pet. at 22-26. Respondent's answer to this argument begins with a mischaracterization of the facts, claiming, with citation to no supporting authority, that the Institute of Medicine ("IOM") Report concluded that "there was no credible evidence of prolonged neurological damage from . . . [DPT] vaccine." Opp. at 5. This is *not* what the IOM Report concluded. As the Secretary herself explained, her Table severely narrowed the scope of injuries eligible for compensation to acute encephalopathy because "[t]he IOM . . . concluded . . . that 'the evidence remains insufficient to indicate the *presence or absence* of a causal relation between DTP and chronic nervous system dysfunction under any other circumstances.' " 60 Fed. Reg. 7678, 7683 (Feb. 8, 1995) (quoting IOM Report Executive Summary) (emphasis added). Thus, the Secretary chose to exclude children from the Program where evidence of causation was uncertain, *see* Pet. at 24-26, in direct conflict with Congress's decision to structure the Vaccine Compensation Program to give claimants the "benefit of the doubt."[3]

Respondent acknowledges that Congress conferred authority on the Secretary in "broad terms" to amend the statutory Table, Opp. at 17, but then never addresses the issue of what guidance the Secretary has been given in

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[3] Respondent and the Federal Circuit are thus also quite wrong when they claim that the Secretary was not making a policy judgment different from that of Congress when she replaced the statutory Table with her own. *See* Opp. at 14; App. 22a.

the face of scientific uncertainty. Respondent simply says that "Congress presumably conferred regulatory authority in those broad terms because it understood that adapting the Initial Table, in light of developing scientific knowledge, would require the exercise of informed administrative judgment that might either increase or decrease the scope of presumptive, Table-based compensability." *Id.* Certainly, scientific conclusions that certain vaccines cause some and do not cause other injuries are the fruit of "developing scientific knowledge." As we noted in our Petition, if the Secretary amends the Table as a result of this developing knowledge, such a change arguably could be shaped by an "intelligible principle" in the Vaccine Act. Pet. at 23. But if the evidence of causation of certain injuries remains "insufficient" to establish the presence or absence of causation, "scientific knowledge" throws no "light" on the question of whether the children who have suffered those injuries should still be benefited by the Table mechanism. And such an administrative judgment cannot be "informed" by science when scientific knowledge has not developed far enough to provide an answer. Science does not guide the Secretary in her "thumbs up" or "thumbs down" in that circumstance. Nothing but her own, "uncanalized" policy preferences induced the Secretary to give a thumbs down on the injuries suffered by Petitioner Julie Terran. *See Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 675 (1980) (Rehnquist, J., concurring).

3. The error below concerning Petitioner's "off-the-Table" claim centers on the special master's conclusion that such claims must be measured "*under the same standards which apply in traditional tort litigation.*" App. 75a (emphasis in original). This error merits this Court's review because it fundamentally disrupts the unique, two-part standard of proof designed by Congress to award compensation under the Vaccine Act. *See* Pet. at 5, 7, 28. The confusion within the Federal Circuit centers not

on the standard of proof itself, which is directly set forth in the statute, but in the interpretation and application of one prong of this standard of proof: the provision that, to award compensation, there must *not* be a preponderance of the evidence that the claimed injury is due to factors unrelated to the administration of a vaccine. 42 U.S.C. § 300aa-13(a)(1)(B). As the Secretary has explained to the Court before, when the government cannot point to such identifiable factors, this provision "requires that the claimant receive the benefit of the doubt on the issue of causation." Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, *Shalala v. Whitecotton*, 514 U.S. 268 (1995) (No. 94-372), at 17.

Yet in this case, reflecting the split of understanding in the Federal Circuit that effectively renders this benefit of the doubt a nullity, *see* Pet. at 26-30, the special master rejected Petitioner's claim even though he concluded that her injuries were *not* caused by "any factor unrelated to the administration of the vaccine." App. 89a. This is not a fact-bound issue as Respondent claims, *see* Opp. at 19, but a legal error that has undermined the promise of the Vaccine Compensation Program as envisioned by Congress. It is not only appropriate, but vitally necessary to the operation of the Program, that this Court restore that promise.

4. Finally, it is worth noting that Respondent has essentially identified no true vehicle problems encumbering the Court's review of this case, instead engaging the issues raised squarely on the merits. In closing with a brief mention of two "factors that weigh against review," Respondent first notes that, should the Court grant review, it might disinter a procedural argument it lost before the Federal Circuit. Opp. at 19. Respondent does nothing more, however, than to state the accepted proposition that a party that has not filed a petition for certiorari may defend a judgment below on any ground that does seek alteration of that judgment. *See, e.g., Northwest*

Airlines, Inc. v. County of Kent, 510 U.S. 355, 364-65 (1994). This is true in every case reviewed by this Court and does not counsel against review in this particular case.

The Respondent goes on to summarily claim that the nonseverability clause in the Vaccine Act "counsels against granting review." Opp. at 20. Here again, if that clause counsels against this Court's review of the constitutional questions raised here, it will always do so, and no case could ever be a vehicle to address the serious constitutional issues that plague the operation of the Vaccine Act. In short, the nonseverability clause offers no basis to conclude that this case is not an appropriate vehicle by which the Court can resolve these critical matters.[4]

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[4] On the merits, if the nonseverability clause invalidates the whole Compensation Program upon a ruling for the Petitioner, then neither she nor any claimant can ever have standing to raise these constitutional issues. Such an absolute bar raises serious constitutional questions of its own, which this Court traditionally seeks to avoid through statutory construction. *See Johnson v. Robison*, 415 U.S. 361, 366-67 (1974); *Webster v. Doe*, 486 U.S. 592, 603 (1988); *Weinberger v. Salfi*, 422 U.S. 749, 762 (1975). Such a construction is readily available here because the nonseverability clause creates only a presumption against severability. *See, e.g., Dorchy v. Kansas*, 264 U.S. 286, 290 (1924); *United States v. Jackson*, 390 U.S. 570, 586 n.27 (1968). Declining to apply the presumption would not conflict with the purpose of the clause, which apparently was to ensure that, if the Vaccine Act's limitations on access to state courts and on tort liability were overturned on constitutional grounds, the Vaccine Act's unique compensation mechanism would also cease rather than leaving intact two separate avenues for compensating injured children. *See, e.g.*, 135 CONG. REC. S16,157 (daily ed. Nov. 17, 1989) (statement of Sen. Kennedy) (nonseverability clause ensures that "entire system of compensation and tort change would fall" if either provision fell). Moreover, the standing issues briefly noted by Respondent are hardly "difficult," Opp. at 20, since in any standing inquiry a plaintiff's merits claims,

CONCLUSION

For the foregoing reasons, and the reasons stated in the petition, the petition for a writ of certiorari should be granted.[5]

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which include the severability issue, are assumed to be true. *See Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (citing *Warth v. Seldin*, 422 U.S. 490, 500 (1975)); *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38 (1976); *Immigration & Naturalization Serv. v. Chadha*, 462 U.S. 919, 936 (1983).

[5] Respondent has submitted one Reply in Opposition to both our Petition for a Writ of Certiorari and to that filed in *O'Connell v. Shalala*, No. 99-1747. Though these cases raise the same constitutional issues, the Federal Circuit set out its opinion in this case, and ruled in *O'Connell* only by reference to its opinion here. *O'Connell* adds no additional facts that illuminate these issues, and thus the Court's consideration of them would not be significantly aided by plenary review of *O'Connell* in addition to this case. In our view, the Court should hold the petition in *O'Connell* pending the disposition of the petition in this case.